UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	Judge Patti B. Saris

PLAINTIFFS' SEPARATE MEMORANDUM IN OPPOSITION TO DEFENDANT-SPECIFIC MEMORANDA ON MOTIONS TO DISMISS (REDACTED VERSION)

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In addition to their Consolidated Memorandum, many Defendants filed Defendant specific memorandum in support of their motion to dismiss. Plaintiffs submit this response to the Defendant specific memoranda.

I. INTRODUCTION

Although 30 Defendants have filed 23 separate Defendant-specific memoranda, for the most part, little is "specific" about the memoranda. The memoranda raise nearly identical and duplicative complaints regarding non-compliance with Rule 9(b), the existence of generic and multi-source products as drugs not properly named in the AWP scheme, and the absence of a particular purchaser for each and every one of the drugs manufactured by a Defendant which are named in the AMCC. Each of these issues is also addressed by Defendants in their consolidated memorandum. This opposition first addresses the common arguments raised in virtually each of the 23 memoranda. Specific issues are addressed seriatim in the order presented in the Defendant-specific memoranda.

II. BACKGROUND

While Plaintiffs recognize that this Court is familiar with the procedural background of this case, Plaintiffs set forth aspects of that background because some arguments rest on the procedural matters of (i) the purposes for drug specification in the AMCC and (ii) the scope of previous discovery from Defendants.

In the fall of 2001, civil litigation relating to average wholesale price manipulation commenced in the wake of a series of governmental reports regarding unlawful manipulation of average wholesale prices. (*See, e.g.*, ¶¶ 155-57, 208, 260, 280, 287, 294, 311, 328, 336, 350 353, 360, 371, 415, 431, 462-63, 466, 478-80, 484, 487, 508, referring to or drawing upon those reports.) While many of those reports focus on abuse within the Medicare Part B system (and its consequent inflation of the 20% co-pay incurred by private payors), the reports also described abuse outside the realm of

physician administered (*e.g.*, injectable) drugs. Those reports – and the rampant pricing abuse being investigated by the many federal and state public agencies involved – overwhelmingly chronicled AWP manipulation with respect to a wide range of oral and injectible drugs, with particular focus on multi-source drugs (*i.e.*, generic drugs, or brand name drugs for which a generic alternative exists). *Id.*

On April 30, 2002, the Judicial Panel on Multidistrict Litigation ("JPMDL") ruled that "all actions . . . involve common questions of fact concerning (either singly or as part of a conspiracy) the pharmaceutical Defendants engaged in fraudulent marketing sales and/or billing schemes by unlawfully inflating the [AWP] of their Medicare covered prescription drugs in order to increase the sales of these drugs to healthcare professionals and thereby boost the pharmaceutical companies' profits." Order at 3, *In re: Pharm. Indus. Average Wholesale Price Litig.*, MDL No. 1456. (Apr. 30, 2002). As a result, the JPMDL issued an order stating that "actions pending outside the District of Massachusetts and listed on the attached Schedule D are transferred to the District of Massachusetts, assigned to the Honorable Patti B. Saris for coordinated or consolidated pretrial proceedings with the action already pending there . . ." *Id.* at 3-4. The JPMDL acknowledged that the cases allege industry-wide abuse with respect to the use of average wholesale price reimbursement systems, and ruled that those claims against multiple Defendants have sufficient common nucleus of fact and law warranting coordinated treatment.

On September 6, 2002, the original Master Consolidated Complaint ("MCC") was filed against 36 Defendants from 22 business operations. Although the MCC specified certain drugs in the text of the allegations, the MCC did not expressly limit itself to a narrow set of drugs manufactured by Defendants for which wrongful AWP manipulation was alleged to exist. As a result, the MCC could fairly be read to raise AWP manipulation regarding ***all*** drugs manufactured by ***all*** Defendants, amounting to thousands of drugs bearing tens of thousands of separate NDC numbers.

Motions to dismiss followed, and during this period the Court permitted a narrow range of discovery to move forward. On October 28, 2002, this Court issued an order (after competing filings by the parties) directing Defendants to produce: (i) documents they had previously produced regarding existing or previous state or federal investigations into the use of AWP in pricing of reimbursement of drugs; and (ii) documents they had previously produced in connection with any other legal proceeding in which the Defendant was alleged to have overstated, misstated a manipulated AWP or otherwise failed to account for certain costs. Plaintiffs were not permitted to move forward with discovery as to any other issues.

Following that discovery order, some Defendants produced those documents that they represented were the set of documents that previously had been produced in other legal proceedings. That production, however, was limited (i) to only those documents that previously had been produced elsewhere, which (ii) related to the scope of the document requests made in those other proceedings, and which (iii) related only to certain drugs as therein requested (*i.e.*, did not relate to the scope of drugs specifically identified in the MCC). As a result, while the magnitude of documents produced was not insignificant, seven Defendants produced no information, and discovery received from the remaining Defendants was narrowly limited. Indeed, only one Defendant produced internal pricing information relating to actual transaction costs for a limited number of drugs.[1]

On May 13, 2003, this Court granted in part, and denied in part, Defendants' motion to dismiss the MCC. *See In re: Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172 (D. Mass. 2003) (hereinafter "*AWP Litig.*" or "AWP"). This Court denied the Defendants' motion to dismiss "with respect to any drug identified in the

[1] This has a direct bearing on Defendants' 9(b) arguments advanced in this current set of motions, *i.e.*, that the AMCC needed to state the amount of the spread. As none of the Defendants have produced actual pricing information for the AMCC drug, the facts as to amount of the spread remain solely within their control.

complaint together with the allegedly fraudulent AWP published by a named defendant for that drug." *Id.* at 194. The Court further stated: "In the event any such amendment is filed, plaintiff shall clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." *Id.*

Following the May ruling, Plaintiffs continued a massive review of each Defendant, its products and its pricing conduct with respect to those products. Plaintiffs continued to use all available public reports, to use all Defendants' documents, and to consult with pharmaceutical industry experts and insiders.

On June 12, 2003 (about four weeks after the May order), Plaintiffs filed a 301 page, 741 paragraph Amended Master Consolidated Complaint. The AMCC includes six sections of factual allegations.

First, the party and drug description section (*i.e.*, the ***who*** of the fraud and wrongdoing) details each Defendant and the drugs in this case in 22 pages containing 125 paragraphs of party and drug descriptions. ¶¶ 26-131.

Second, general allegations "applicable to all Defendants" are set forth in 31 pages containing 87 paragraphs. ¶¶ 1-11, 132-99, 541, 595-603. These general allegations (*i.e.*, the ***how*** and ***when*** of the fraud and wrongdoing) describe common, fraudulent AWP practices engaged in by Defendants with respect to both oral and injectible pharmaceutical products. For injectibles and other provider-administered drugs, Defendants inflate the AWP to effectuate over-reimbursement to the providers (who purchased the products for administration to patients). For orally-administered drugs, Defendants inflate the AWP in order to effectuate over-reimbursement (and thereby also disguise hidden financial arrangements with) pharmacy benefit managers and others in the drug distribution chain.

Third, the AMCC contains 23 subsections of Defendant specific allegations in 133 pages containing 340 paragraphs. ¶¶ 200-540. The Defendant-specific allegations (*i.e.*, examples of the ***how***, ***what*** and ***when***)[2] each set forth a chart naming the precise drugs at issue in the case, and provide examples of Defendants' wrongful conduct and AWP "spread."

Fourth, a section describing the Together Rx Card scheme contains 17 pages comprising 17 paragraphs. ¶¶ 23, 542-94. In addition to describing a conspiracy among many Defendants in the case to raise the AWP in order to reimburse pharmacies and others in the distribution chain, the Together Rx allegations also elucidate another manner in which the Together Rx Defendants manipulate AWP for profiteering purposes.

Fifth, the AMCC attaches an Appendix A that details each drug, each NDC for each drug, and each AWP for each of one or more of 6 one-year periods, which limits the drugs and fraudulent AWP for those drugs (AMCC, App. A). Appendix A sets forth the ***what*** and ***when*** of the fraud and the unlawful conduct by setting forth the fraudulent AWP for each drug (by NDC number) at issue in the litigation. Appendix A does not seek to ***quantify*** the ***extent*** of Plaintiffs' damages nor the calculation of the extent of AWP manipulation. Appendix A does not attempt, therefore, to calculate the "spread" as some defendants now demand in their motions. The Order did not require identification of the spread, but required identification of the inflated AWP. So, for example, Defendant Abbott, reviewing Appendix A, would be on notice for the drug Biaxin, with an NDC Code of 0074-3368-11, and the fraudulent AWPs of $345.10; $345.10; $372.60; $378.28; $396.72 and $437.98, for the years 1997-2002 respectively. Each Defendant is put on notice in a similar fashion.

Finally, the AMCC contains an Appendix B, which specifies for each of the six third party payors the specific drugs it purchased. So, for example, Defendant Abbott as

[2] *See United States ex rel Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (Saris, J.).

to Biaxin, can examine Appendix B and see that each of the third party payors purchased Biaxin.

Consistent with the reality that this consolidated litigation applies to multiple pharmaceutical companies alleging common issues of AWP manipulation, and that Rule 8 should have meaning here, the AMCC also details in numerous pages the manner and methods by which "all Defendants" manipulate the average wholesale price in order to effectuate over reimbursement for their pharmaceutical products as a manner and method of doing business, and fostering the use of their products. *See* ¶¶ 133-98. Although these common allegations are almost universally ignored in the Defendant-specific memoranda, those allegations expressly apply "to all Defendants." Plaintiffs allege, and intend to prove, a common course of business practice by and among Defendants regarding over reimbursement for specified drugs (regardless whether the drugs are being reimbursed by public payors or private payors, and regardless whether they are generic drugs, multi-source brands or brand name drugs for which no bio-equivalent currently exists in the marketplace). Although the AMCC is an obviously large and detailed document that alleges sweeping wrongdoing by Defendants, the AMCC focuses on 321 drugs manufactured by Defendants (as against the universe of approximately 65,000 currently-FDA approved drugs in the United States marketplace).

III. COMMON ARGUMENTS REPEATED THROUGHOUT THE "DEFENDANT-SPECIFIC" MEMORANDA

A. The "No Fraudulent AWP" Argument Raised By Most Defendants Lacks Merit

In the Defendant-specific memoranda, many Defendants argue that the AMCC fails to allege "a fraudulent AWP" for some or all of the drugs at issue in this case.[3] However, Defendants' cannot seriously maintain there is "no fraudulent AWP" stated for every drug at issue in the AMCC. In fact, the AMCC painstakingly and clearly sets forth

[3] *See, e.g.*, Abbott at 3; Aventis at 5; Bayer at 4; Braun at 3; BMS at 3; Fujisawa at 2; and Hoffman at 3.

the fraudulent AWP for every drug by setting forth, in Appendix A, the specific drug, the NDC number[4] and the specific AWP that a specific Defendant caused to be fraudulently posted as the average wholesale price. Defendants cannot credibly argue that there is "no fraudulent AWP" for each drug.

Instead, Defendants' argument appears to be that for some drugs the AMCC does not ***quantify the amount*** by which the fraudulent AWP exceeds true transaction amounts, or true average wholesale price. In effect, Defendants argue that Fed. Rules 8 and 9(b) require the AMCC to estimate damages, or to quantify the amount by which each published average wholesale price exceeded a good faith estimate of true transaction amounts; that quantification should have been alleged for each drug. The grounds argued by Defendants to require quantification of every AWP inflation lack merit.

First, the AMCC faithfully follows the directives of this Court in its May 13 Order. That Order requires that the AMCC identify "the specific drug or drugs that were purchased from the defendant [and] the allegedly fraudulent AWP for each drug." *AWP Litig.*, 263 F. Supp. 2d at 194. During the course of this litigation, Plaintiffs' counsel has conducted an exhaustive search (on the basis of available information), reviewed thousands of potential drugs and pricing behavior of Defendants, reviewed competitive positions, and gathered significant information from pharmacy industry insiders, experts and other sources. In the weeks following this Court's May 13 Order, the AMCC narrowed the range of specific drugs at issue in this case. In the text of the AMCC (¶¶ 201-540), the AMCC sets forth numerous examples of AWP fraudulent inflation using, at times, estimates of that inflation based upon information (other than from the files of Defendants). The AMCC sets forth the fraudulent AWP for each of 321 drugs in Appendix A (by each NDC number for each drug), and in doing so identifies "the allegedly fraudulent AWP for each drug" at issue in the case.

[4] The National Drug Code (NDC) is a 10-digit, 3-segment number that identifies the labeler/vendor, product (specific strength, dosage form and formulation for a particular firm) and trade package size.

Defendants seem to argue that the May 13, 2003 Order of this Court required ***quantification*** of the extent AWP inflation for each drug. This cannot be found in the text of the Court's Order, nor in any rule of court. *See, e.g., Treadwell v. John Hancock Mut. Life Ins. Co.*, 666 F. Supp. 278, 285-86 (D. Mass. 1987) (despite the lack of specific damage amounts, the Court stated that "the precise manner in which plaintiff was allegedly harmed is a matter of proof, not pleading" and that at "the pleading stage such damages are sufficiently defined and amenable to specific proof as to be legally cognizable"); *see also Shapiro v. UJB Fin. Corp.*, 964 F. 2d. 272, 284 (3d Cir. 1992) (stating that Rule 9(b) is satisfied or the Plaintiff simply alleges that "the plaintiff acted upon it to his damage"). The purpose of setting forth the fraudulent AWP was, as the Court indicated, to clearly identify the precise drugs at issue in the case, coupled with the fraud being perpetrated by Defendants with respect to the designated drugs. This the AMCC accomplishes.

Second, only Defendants have access to the internal pricing information that would make possible quantification of the extent by which a fraudulent AWP for a drug exceeds the true transaction average of wholesale prices. No Defendant makes this information available publicly; Defendants' actual transaction, price and cost information is maintained highly confidential. Only one Defendant has, to-date, made that information available in discovery. Actual transaction cost and pricing information is available from no other source, and Defendants are aware of this fact. Accordingly, Defendants seek to impose a requirement they know Plaintiffs cannot meet – quantification of the extent of AWP price inflation without access to the only source of information upon which that quantification could be made, *i.e.*, Defendants' own internal cost and price information. Courts do not place a burden to quantify damages or plead detailed facts that are outside the reach of Plaintiffs. *See, e.g., New England Data Servs., Inc. v. Becher*, 829 F.2d 286, 290-91 (1st Cir. 1987) (when information is beyond the grasp of the Plaintiffs and within the province of Defendants, a RICO claim should not be

dismissed on a Rule 9(b) basis without first affording Plaintiffs additional discovery providing such information).

Third, at this procedural stage the AMCC places Defendants on notice of all of the substantive facts and claims in the case; it delimits the exact drugs at issue in the proceedings; it articulates the ***who*** (each of the Defendants), the ***what***, ***when*** and ***where*** (through repeated publication of purported average wholesale prices for specified drugs) and the ***how*** (the provider, PBM and other distribution chain profit incentives, undisclosed kickbacks, rebates, discounts and off invoice pricing, etc.) in the case. Each Defendant now knows which of its drugs to defend and the nature of the allegations raised against that Defendants' conduct.

Defendants appear to be arguing that the anecdotal examples of AWP price spreads set forth in the text of the AMCC should both (i) be interpreted as efforts to quantify precise AWP price inflation; and (ii) serve to delimit the price spreads, and eventual damages, that might be argued in this case for each drug. The assumptions are untrue and disclose a misunderstanding of the AWP investigations. In recent years various public agencies have chronicled AWP price inflation by most of the Defendants in this case. In doing so, ***none*** of those agencies have had access to accurate transaction costs or pricing information. Given the absence of accurate transaction cost information from Defendants, those public agencies (as is the case with Plaintiffs' counsel here) look to alternative sources of pricing information recognizing, quite explicitly, that those alternative sources of information will not give a precise quantification of AWP inflation (and, in fact, are almost always likely to yield an underestimation of price inflation). For example, the OIG – recognizing that it does not have available to it accurate transaction cost information, which information is only available from the Defendants – has used comparisons of AWP to manufacture catalog prices; wholesale price lists; and to prices available to other governmental agencies, including the Veteran's Administration and various state Medicaid programs, as well as to direct retail purchasers. Thus, price

inflation estimation by using catalogs, federal price schedules and other rough estimates of actual transaction cost information is but ***one*** tool by which to detect manipulation of AWP price setting for the purposes of creating profit incentives to participants in the distribution chain. Resort to these estimation tools is necessary because, without internal transaction data from pharmaceutical companies themselves, no reasonably precise calculation of the inflation is possible.

Finally, it is important to note the pleading game being played here. Defendants did not raise this "spread" argument in the initial round of motions directed to the MCC.[5] Each iteration of the complaint is being subject to heightened and changing 9(b) demands by Defendants, which will be a never-ending. One Defendant goes so far as to demand that plaintiffs identify "where" each drug was purchased. If Plaintiffs included the spread information, then more demands would be made under the guise of 9(b) motions and the process would never end.

In summary, the AMCC clearly delineates each drug in the fraudulent AWPs for that drug. Frequently, but not always, some examples are provided for drugs regarding estimations of the amount by which the AWP has been inflated, but those examples do not become the standard bearer of pleading. Instead, multiple other sources of information are available to determine fraudulent inflation of AWPs, and a quantification of that fraud will be possible when discovery is afforded into actual transaction cost and price information available solely in the books and records of each Defendant.

B. Plaintiffs Have Adequately Alleged the Circumstances of the Fraud

All of the Defendants in their "specific memoranda" argue the alleged 9(b) deficiencies of the AMCC. The arguments lack merit.

Consistent with this Court's ruling in *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d at 46, Plaintiffs have "allege[d] the circumstances of the fraud"

[5] *See, e.g.*, Abbott initial Defendant-specific memoranda at 2-4, where the issue is not raised; Bayer, initial defendant specific memorandum, this issue is not raised.

but are "***not*** required to plead ***all*** of the evidence or facts supporting it." *Id.* at 46-47 (emphasis added); *see also id.* at 46 ("The requirements of Rule 9(b) . . . must be read in conjunction with Fed. R. Civ. P. 8(a)," which requires only a "short and plain statement of the claim."). Indeed, the Court has recognized that "where the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible." *Id.* at 49.

The *Parke-Davis* ruling is in accord with other decisions from this District, including *In re Xcelera.com Sec. Litig.*, 2002 U.S. Dist. Lexis 7400, at *7-8 (D. Mass. Mar. 8, 2002), where Judge Zobel applied Rule 9(b) and sustained plaintiffs' securities fraud claim because the complaint cited to nine investigative sources and identified and quoted from "supporting documentation to buttress the[] allegations;" and Senior Judge Caffrey's decision in *Kuney Int'l, S.A. v. DiIanni*, 746 F. Supp. 234, 237 (D. Mass. 1990), where the Court commented that Rule 9(b) is satisfied where "[t]he general outline of the general scheme to defraud . . . provides the defendant with notice of the grounds on which the plaintiff's claim is based."

Here, the "circumstances of the fraud" and the "general outline of the general scheme to defraud" are as follows. Plaintiffs allege that Defendants inflate average wholesale prices ("AWP") for drugs covered by Medicare Part B and then market the spread between the Medicare reimbursement rate or the private reimbursement rate and the providers' acquisition cost. Through this AWP Scheme, Defendants incentivize providers to administer the drugs for which Defendants have created the biggest spread and, thereby, increase sales for the drugs and their market share. ¶¶ 160-63. Plaintiffs and members of the AWP class as defined by the AMCC are damaged by paying inflated co-pays for the drugs. ¶¶ 541, 595.

For brand name and generic drugs administered outside of the Medicare Part B context, Plaintiffs allege that Defendants specifically marketed the inflated AWP – the price on which Plaintiffs' payments in the private reimbursement market are based – to

pharmacy benefit managers ("PBMs") and other intermediaries in order to induce them to place those drugs on their formularies. ¶¶ 171-73. The AWP Scheme incentivizes intermediaries to place drugs on formularies based not on their professional judgment but, instead, on their desire to increase their profitability. Plaintiffs allege that PBMs and other intermediaries pocketed the "spread" between AWP and the actual cost paid for those drugs. ¶¶ 175-78.

In the AMCC, Plaintiffs apply these "circumstances of the fraud" to each Defendant. At the beginning of Section V of the AMCC, entitled "Examples of Unlawful Conduct," Plaintiffs describe the specific unlawful conduct of each named Defendant in great detail. ¶¶ 200-540. Further, at the end of almost every Defendant-specific section, Plaintiffs provide specific examples of actual spreads, comparing actual prices offered to customers of each Defendant to the fraudulent AWPs set forth for those drugs in industry compendia. *See, e.g.*, ¶¶ 213-16 (Abbott); ¶¶ 268-70 (Aventis); ¶¶ 283-84 (Baxter); ¶¶ 324-26 (B. Braun); ¶ 360 (Dey); ¶¶ 371-75 (Fujisawa); ¶ 472 (Pharmacia); ¶¶ 502-03 (Sicor); ¶¶ 535-36 (Watson). Notably, these specific allegations at times derive from documents produced by Defendants to governmental investigative sources, and are – in the words of Judge Zobel – quoted from "supporting documentation to buttress the[] allegations" of the general scheme to defraud. *In re Xcelera.com Sec. Litig.*, 2002 U.S. Dist. Lexis 7400, at *8.

Plaintiffs respectfully submit that they have satisfied Rule 9(b)'s particularity requirement by clearly setting forth the "general outline of the general scheme to defraud" which is sufficient to "provide[] the defendant[s] with notice of the grounds on which the plaintiff's claim is based." *Kuney*, 746 F. Supp. at 237. In fact, Plaintiffs have far exceeded this requirement by citing specific documents from Defendants that directly support the AWP scheme outlined in the AMCC. Plaintiffs have also satisfied the Court's Order and provided a fraudulent AWP for each of the drugs at issue in the AMCC.

At this stage of the proceedings, it is not possible for Plaintiffs to quantify ***the specific fraudulent spread*** associated with each drug because the facts necessary to make such calculations – namely the actual wholesale transaction prices of these particular drugs and the variety of hidden incentives that Defendants employ to reduce the listed prices of drugs – are peculiarly within the Defendants' control. Indeed, as this Court recognized in *Parke-Davis*, "where facts underlying the fraud are 'peculiarly within the defendants' control,' a plaintiff may be excused from pleading the circumstances of the fraud with a high degree of precision." 147 F. Supp. 2d at 47 (quoting *Boston & Me. Corp. v. Hampton*, 987 F.2d 855, 866 (1st Cir. 1993)).[6]

C. Generic and Multi-Source Drugs Fit Within the AWP Scheme

Virtually every Defendant claims that generic or multi-source drugs do not fit within the AWP scheme. This issue was raised in the consolidated memorandum as well, and Plaintiffs refer the Court to that response as opposed to fully responding to the 23 memoranda raising the exact same issue.

D. Plaintiffs Have Standing to Sue on All Drugs Identified in the AMCC

Several Defendants, in their individual briefs, argue that Plaintiffs lack standing as to certain drugs because the AMCC fails to identify a plaintiff-purchaser for those drugs.[7] According to Defendants, Plaintiffs' inability to name a purchaser for every drug violates the Court's May 13, 2003 Memorandum and Order which stated that Plaintiffs should allege for each Defendant "'the name of the specific plaintiff(s) that purchased the drug.'" However, in their zeal to knock out Plaintiffs' claims, Defendants ignore the Court's juridical link analysis and, as a result, misconstrue the Court's opinion.

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[6] Plaintiffs do concede that there are methods one can use to estimate the spread based on information plaintiffs do have and plaintiffs can do so if required. However, the exact spread can only be alleged after review of Defendants' documents.

[7] *See* Abbott Labs. at 1-2; AstraZeneca at 3 n.4; Aventis at 2-3; Baxter at 1; Bayer at 1-5; Boehringer at 1-2; B. Braun at 2-3; Fujisawa at 4-5; GSK at 1, 2 n.1; Hoffman-LaRoche at 3; Immunex at 2; Novartis at 2-3; Pharmacia & Upjohn at 2; Schering-Plough at 1; Gensia Sicor at 2; Warrick at 3; Watson at 1, 3-4.

This is not the first time that Defendants have attacked standing on this ground. Defendants previously (and unsuccessfully) argued that the Court should dismiss all claims in the MCC relating to drugs for which there was no identified plaintiff-purchaser because Plaintiffs lacked standing and could not show a sufficient juridical link between the Defendants to satisfy any exceptions to the standing requirement. Yet despite Defendants' protestations, the Court rejected the argument that the juridical link doctrine was inapplicable to the case, explaining:

> For present purposes, I decline defendants' invitation to determine whether a plaintiff who purchased one drug from a given company has standing to represent a class of others who purchased a different drug or drugs from the *same* company. Those allegations fit better into the juridical linkage claim, and the issue will be decided at a later stage in the litigation. [*AWP*, 263 F. Supp. 2d at 193-94 (citing *Ortiz v. Fibreboard Corp*, 527 U.S. 815, 831 (1999)).]

Here, the allegations in the AMCC are entirely consistent with the Court's Order. As an initial matter, the AMCC, like the MCC, alleges a juridical link between all Defendants. As this Court recognized, "[s]ome courts have carved out an exception to the standing requirement in cases in which all defendants are juridically related in a manner that suggests that a single resolution of the dispute would be expeditious." *AWP*, 263 F. Supp. 2d at 193. Here, the AMCC avers that each Defendant engaged in the common practice of inflating their respective AWPs under the same statutory structure (Medicare Part B) in an effort to increase their market share and profit, as well as to disguise kickbacks and other wrongful remuneration. ¶¶ 3, 4, 7. The AMCC further alleges that the inflated AWPs also were used as a benchmark for reimbursement outside the Medicare Part B context where non-Medicare patients and health plans paid PBMs for drugs based on their respective AWPs. ¶ 5. Under both practices, each Defendant used the same agents in the *Red Book*, *Blue Book* and *Medi-Span* to accomplish their unlawful ends and publish their fraudulently inflated AWPs. ¶¶ 160-62; *see also Weld v. Glaxo Wellcome Inc.*, 434 Mass. 81, 91 (2001) (finding that plaintiffs had standing to sue

defendant pharmaceutical companies with whom they had no direct connection because the defendants all used the same entity to distribute their letters to pharmacy customers). Because the overinflated AWPs reported by Defendants underlie each of the claims set forth in the AMCC, a single resolution of the dispute would be expeditious. *See Payton v. County of Kane*, 308 F.3d 673, 678-80 (7th Cir. 2002) (holding that even though six named plaintiffs had direct claims against only two defendants, plaintiffs had standing to sue nineteen defendant counties whose common course of action arose out of the same statute and thus was juridically linked); *Alves v. Harvard Pilgrim Health Care, Inc.*, 204 F. Supp. 2d 198, 205 (D. Mass. 2002) (Saris, J.) (holding that plaintiff who had a claim against one ERISA plan had standing to represent a class of plaintiffs who were in other ERISA plans with different sponsors), *aff'd*, 316 F.3d 290 (1st Cir. 2003). Thus, each of the Defendants is juridically linked.

Moreover, and as referenced throughout, the AMCC fully complies with the Court's Order. For example, Plaintiffs no longer assert claims against a Defendant from which ***no*** named Plaintiff purchased a drug. *See* Order at 41-42. Rather, in accordance with the Court's clear directive, Plaintiffs only assert claims against Defendants that manufactured and/or marketed at least one drug ***actually reimbursed*** by a Plaintiff. *See* Appendix B to the AMCC. Even Defendants do not dispute this fact. Plaintiffs' inability to specify a purchaser for ***each and every*** identified drug is hardly improper where the Court already stated that claims involving one drug reimbursed by a Plaintiff "fit better" into Plaintiffs' juridical linkage argument *vis-à-vis* standing to sue on other drugs manufactured and/or distributed by that ***same*** Defendant (thereby compelling full resolution of the juridical link issue at a later stage in the litigation). 263 F. Supp. 2d at 194.

In their defendant-specific memorandum, defendants all argue that to allege standing, Plaintiffs "must allege personal injury fairly traceable to the defendant's unlawful conduct and likely to be redressed by the requested relief." *See, e.g.*, Abbott

Mem. at 2. The AMCC alleges a broad scheme on behalf of each Defendant to use AWP, and inflated AWPs, as an industry reimbursement benchmark. ¶¶ 138, 140-41, 162, 168-90. Plaintiffs' injury, payment for inflated drugs, is directly traceable to this overarching scheme. And the redress, sought in part by way of a declaratory judgment requiring an accurate published AWP in the future, is likely to be accomplished regardless of specific drug purchases. Thus, under defendants' own standard, Plaintiffs have standing as to all drugs identified in the AMCC.

The AMCC's conspiracy allegations provide Plaintiffs with an additional, independent exception to standing that was not before the Court during briefing on the MCC. Courts hold that an exception to standing exists when the plaintiffs' injuries result from a conspiracy between defendants. *See La Mar v. H & B Novelty & Loan Co.*, 489 F.2d 461, 466 (9th Cir. 1973) (holding that the two exceptions to standing are: (i) where all injuries are the result of a conspiracy or concerted schemes between the defendants at whose hands the class suffered injury, and (ii) where all defendants are juridically related); *AWP*, 263 F. Supp. 2d at 193 (stating "'Post-La Mar cases from other courts have suggested that if all the defendants took part in a similar scheme that was sustained either by a contract or ***conspiracy***, or was mandated by a uniform state rule, it is appropriate to join as defendants even parties with whom the ***named*** class representative did not have direct contact.'" (Emphasis in underline added.)). Here, Plaintiffs have alleged two civil conspiracy claims against Defendants and injuries resulting therefrom. Count IX alleges a claim against Defendants Abbott, Amgen, AstraZeneca, Aventis, Baxter, Bayer, BMS, GSK, Hoffman-LaRoche, Immunex, J&J, Pfizer, Pharmacia, Schering-Plough, Sicor, TAP, Watson, Warrick, Dey, Boehringer, B. Braun and Fujisawa for engaging in a series of separate civil conspiracies with each of the PBMs to overinflate AWPs. ¶¶ 726-33. Likewise, Count X alleges a conspiracy claim against the Together Card Defendants Abbott, AstraZeneca, Aventis, BMS, GSK, J&J, Novartis and

TAP. ¶¶ 734-41. Because the AMCC alleges that Plaintiffs' injuries resulted from these conspiracies (¶¶ 733, 741), Defendants' standing challenge must fail.

IV. ARGUMENT – DEFENDANT SPECIFIC

Plaintiffs now turn to a Defendant by Defendant response.

A. Abbott

1. Review of Abbott allegations

In the AMCC, Plaintiffs allege specific facts against Abbott Laboratories ("Abbott"). *See* ¶¶ 201-16. The AMCC states, and several governmental investigations have confirmed, that Abbott created and implemented a fraudulent scheme to artificially elevate prices charged for twenty-six (26) specific drugs in order to increase sales volume and market share of those drugs at those elevated prices. *See* ¶¶ 201-02. The AMCC details by way of example, the estimated spread for specific Abbott drugs. ¶¶ 208, 214. The twenty-six drugs for which Plaintiff alleges Abbott has stated a fraudulent AWP have been set forth in Appendix A to the AMCC, and are delineated by manufacturer, product name, generic name, NDC number and fraudulent AWP for varying years. Further, Appendix B to the AMCC references those specific employee benefit plan Plaintiffs that purchased any of the twenty-six drugs manufactured by Abbott.

The AMCC further alleges that Abbott has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia for the purpose of manipulating the spread in order to maximize profit to its providers and other intermediaries at the expense of Plaintiffs and Class members. ¶ 204. In fact, in response to government subpoenas, Abbott produced many price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and intermediaries which reveal that Abbott consistently offered hundreds of its drugs to its customers at prices significantly below the published AWP. ¶ 213. The AMCC alleges, and cites documentary evidence to support the allegation, that Abbott was aware of how its customers were using the

spread and that Abbott even tracked the AWPs of its generic competition to compare to the AWP of its own generic drugs. *See* ¶ 206.

2. The Abbott-specific arguments lack merit

a. Standing

Abbott does not dispute that Appendix B identifies a Plaintiff who purchased AWP inflated drugs from Abbott. Rather, Abbott claims that as to 14 drugs, because no purchasers are identified, Plaintiffs lack standing. This argument is addressed in Section III., D., *infra*.

b. The AMCC identifies the fraudulent AWP

Abbott claims that for eight drugs there is no "fraudulent AWP." Apparently Abbot concedes that paragraphs 201-15 properly alleges fraudulent AWPs as to the other 12 drugs that are named in the AMCC. As to seven of the eight, the Complaint complies with the Court's Order and identifies the fraudulent AWP by listing the AWP by year, WDC code and amount in the Appendix A. As explained above, Plaintiffs were not required to plead the actual spread as Abbott now demands (but did not demand in its motion directed toward the MCC). As to Liposyn II, its AWP was inadvertently omitted from Appendix A and plaintiffs will correct that omission if acceptable to the Court.

c. Multi-source and generic drugs

Plaintiffs have responded to the generic and multi-source issue in the consolidated memorandum, but as to Abbott the AMCC provides examples as to how Abbott abused the AWP system with respect to generics. *See, e.g.*, ¶ 208 (spreads of 6,037%; 15,671%; 20,735%), and ¶ 214, identifying examples of Abbott's use of generics in the AWP scheme.

d. Five drugs not covered by Part B

Abbott argues that "all Medicare-related claims should be dismissed" as to five drugs that "are not covered by Medicare Part B." Abbott Mem. at 4.[8] As the AMCC makes clear, the AMCC charges AWP inflation both with respect to Medicare-coverable drugs as well as a much broader range of self-administered oral pharmaceuticals. If a drug product is not coverable under Medicare Part B (typically a self-administered oral drug), the AMCC does not allege Medicare-related claims with respect to it. Accordingly there is nothing to dismiss.

Abbott claims that two drugs (Aminocyn and Liposyn II) are covered by Medicare Part B but are subject to "a fee schedule not tied to AWP." Abbott Mem. at 4. *See* 42 CFR § 414.102 (2001); 66 Fed. Reg. 45, 173 (Aug. 28, 2001). However, the regulation to which Abbott refers did not go into effect until January 1, 2002; prior to then, Aminocyn and Liposyn II were reimbursed under Medicare Part B on a "reasonable charge" basis and, as the AMCC alleges, it appears that carriers administering Medicare claims employed AWP to determine reasonable charges.[9] Moreover, the AMCC also alleges AWP inflation regarding Aminocyn and Liposyn II outside the Medicare context as it does for all drugs in the AMCC. *See, e.g.*, ¶ 168. Accordingly, Abbott's argument "that no AWP-based claims can be maintained in the Medicare context as to these drugs" is without merit.

e. Plaintiffs were not required to name a competitor

Abbott also complains that the AMCC does not "identify a competitor against whom four single source drugs . . . compete on the 'alleged spread.'" Abbott Mem. at 5. Of course, Abbott cites no authority for the proposition that the AMCC must identify by name each competitor for each drug because no such authority exists. The AMCC details the drugs, the therapeutic category and the manner in which Abbott fraudulently inflates

[8] The 5 drugs are Biaxin™, Depakote™, Ery-Tab, Erythromycin and Prevacid™, each of which are self-administered oral drugs.

[9] *See* Consolidated Opposition at Section VIII.A.

AWPs in order to create a spread and market profit rather than product. Indeed, Abbott is one of the two co-venturers in the marketing and sale of Lupron, the most notorious example of AWP fraud.[10] Abbott spends tens of many millions of dollars marketing and promoting the four brand name drugs identified in the AMCC; it knows which drugs compete for market share and no legitimate purpose will be served by complying with a hyper-technical requirement of identifying by name each competitor for each of those four drugs. For example:

> Prevacid is a proton-pump inhibitor indicated in the treatment of ulcers and other disorders associated with excess stomach acid. Abbott competes directly with other companies in this market, including head to head with AstraZeneca's Prilosec and its later Nexium. The brand name drugs in this therapeutic regime have huge sales (Prevacid's 2001 sales exceeded $2.9 billion). Abbott doesn't need the AMCC to tell it the products against which Prevacid competes.
>
> Depakote is a coated tablet anti-convulsant indicated as a mono or add-on therapy for simple and complex absence seizures and complex partial seizures in the treatment of the manic phase of bi-polar disorder. Abbott competes directly in this category with Pfizer's Neurontin, and in recent years Abbott stepped up its marketing campaign for Depakote with the aim or warding off additional competition from Lilly's schizophrenia drug Zyprexa. Abbott's 2001 sales for Depakote exceeded $850 million in the United States alone.
>
> Biaxin is an oral antibiotic indicated in the treatment of ear, respiratory tract, skin and skin-structure infections, and is a triple therapy for the eradication of H. Pylori in duodenal ulcers. Abbott's Biaxcin competes directly with Pfizer's Zithromax, which in 2001 was the world's leading macrolide in similar type antibiotic. Biaxin is second in this product category. In recent years Biaxin was losing market share to Pfizer's Zithromax, although Abbott's 2001 United States sales exceed one-half billion dollars.
>
> Calcijex is a parenteral vitamin indicated in the management of bone diseases due to renal failure and hemodialysis patients. Calcijex competes with Roche's

[10] *See* ¶ 508 regarding Lupron.

Rocaltrol. Calcijex is an injectible product marketed directly to providers.

As can be seen, these four single source Abbott drugs are high volume, high sales items for the Abbott organization, and Abbott is well aware of the competition it faces from other products in the same therapeutic categories. Abbott does not need the AMCC to educate it regarding the identity of its competitors.

f. Prevacid is properly in the Complaint

Abbot argues that the AMCC "incorrectly identifies Prevacid® as an Abbott product [when] in fact, Prevacid® is a product of TAP Pharmaceutical Products, Inc." This is a disputed issue of fact, and the allegations of the AMCC control in this Rule 12(b)(6) context. Plaintiffs are aware that Prevacid® is a product marketed by TAP, and the AMCC so alleges in the TAP section of the complaint. However, the AMCC ***also*** alleges, (and Plaintiffs intend to prove) that Abbott (which is one of two co-venturing pharmaceutical companies involved in TAP, "TAP" standing for Takeda Abbott Pharmaceuticals) is directly involved in the manufacturing, marketing, distribution and/or sale of Prevacid®. Indeed, the Together Rx program identifies Prevacid® as a product brought to the Together Rx program "from founding member company Abbott Laboratories." Moreover, TAP's Defendant-specific memorandum (the company that Abbott claims is solely responsible for Prevacid® argues that TAP plays no role in the participation of Prevacid® in the Together Rx Card program, that it is Abbott which markets Prevacid® through the program. Put simply, it appears that Abbott and TAP are pointing the finger at each other for the responsibility of Prevacid®.

B. Amgen

1. Review of Amgen allegations

In the AMCC, Plaintiffs allege that Amgen, Inc. ("Amgen") engaged in an ongoing deliberate scheme to inflate the reported AWP of its drugs, utilize hidden rebates and financial inducements to its customers, and market the resulting spread to increase

the market share of its drugs. *See* ¶¶ 217-30. The AMCC states that Amgen has reported fraudulently inflated AWPs for six (6) drugs. *See* ¶ 217.

In Appendix A to the AMCC, six drugs are identified for which Plaintiffs allege Amgen has inflated the AWPs. The Appendix delineates each drug by manufacturer, product name, generic name, NDC number and fraudulent AWP for varying years. Further, Appendix B to the AMCC references those specific employee benefit plan Plaintiffs that purchased any of the six drugs manufactured by Amgen.

The AMCC further states that Amgen utilized hidden inducements to provide purchasers with substantial discounts in an effort to gain their patronage, but at the same time maintained the fiction of a higher wholesale price. *See* ¶ 226. In addition, Amgen deliberately concealed its fraudulent reporting and marketing of the AWP spread through rebates to at least its Epogen customers. *See* ¶ 220. This had the effect of lowering the true price charged. The government has documented inflated AWPs for both epoetin alfa and filgrastim, and Amgen's own public documents acknowledge that Amgen relies heavily on the reimbursement system to push or maintain market share for those products. ¶ 220.

Amgen's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and Class members. ¶ 230.

2. The Amgen-specific arguments lack merit

The main thrust of Amgen's specific argument is that the AMCC's allegations may only be read to ascribe "guilt by association" to Amgen. This is not the case. The AMCC alleges that Amgen – a manufacturer that focuses on a few products all of which are reimbursable under Medicare Part B – systematically inflates the AWP for each of its few drugs in order to create profit incentives to providers for others in the drug distribution chain. Competitors for each of those drugs are identified because, as a matter

of historic fact, Amgen has gone toe-to-toe with these manufacturers (sometimes in highly acrimonious ways) to compete for market share, and in doing so has used the tool of AWP inflation (as has also been the case with its competitors). ¶¶ 222-23. And the GAO has reported that Epogen accounted for the second highest percentages of Medicare reimbursement and unlike most of the Defendants, Amgen refused to provide GAO with information regarding rebates. ¶¶ 227-29. It is not unreasonable to infer from the information generally available, that disclosure of the rebates would have revealed AWP manipulation.

Amgen also strenuously argues that claims against it should be dismissed with prejudice given "the benefit of limited discovery" provided to Plaintiffs. However, Amgen knows that Amgen ***has provided absolutely no discovery whatsoever to Plaintiffs***.[11] Amgen has repeatedly heralded (in and out of court) that it has never produced documents to any governmental agency relating to its AWP practices. The prior orders of this Court relating to discovery have ordered only those Defendants who have produced discovery to governmental agencies to share that information with Plaintiffs' counsel. Amgen has never done so, and cannot now claim that Plaintiffs have been afforded discovery regarding Amgen's AWP practices.

Moreover, while Amgen attacks the "logical inference" that Amgen has engaged in over-reimbursement as a corporate-wide mechanism to gain market share, Amgen ignores that it has endorsed this corporate practice and acknowledged it in litigation regarding its over-reimbursement policies. In *Amgen, Inc. v. Scully*, 234 F. Supp. 2d 9 (D.D.C. 2002), Amgen filed suit against HHS attacking a proposed HHS rule that would take reimbursement for Amgen's Aranesp out of the AWP system and put it into a direct "pass-through" regime. The proposed regulation would not, of course, inhibit Amgen in any way with respect to the actual prices it could charge its customers. Nor did it affect

[11] *See* Motion for Limited Discovery being filed contemporaneously with this opposition.

Amgen's customers' ability to negotiate actual purchase prices with Amgen. Instead, the proposed regulation simply would affect the manner in which Amgen's customers would be reimbursed by Medicare for their Aranesp purchases. (Meanwhile, one of Amgen's archrivals, Ortho Biotech Products, LP, a subsidiary of Johnson & Johnson and manufacturer of Procrit, also sought to intervene in the case; it, too, saw a significant competitive edge to seeking to enforce the proposed regulation which would give Amgen a disadvantage, and Ortho an advantage, in marketing the spread for reimbursement dollars in this competitive therapeutic category). Amgen argued that it nevertheless had standing to complain.

The *Amgen* court rejected Amgen's argument, stating that it "appears to the Court that the interest plaintiff [was] seeking to protect is its own competitive interest in financial gain." *Id.* at 37. The Court then cited to *TAP Pharms. v. United States HHS*, 163 F.3d 199 (4th Cir. 1998) (in which TAP, the manufacturer of Lupron who eventually paid $875 million for its abusive trade pricing practices, attacked proposed HHS reimbursement charges for Lupron), and observed that Amgen's arguments – in an effort to protect its over-reimbursement marketing strategies – were identical to the interests that TAP sought to protect in *TAP Pharmaceuticals*:

> . . . Like the drug manufacturer plaintiff in *TAP Pharmaceuticals,* Amgen asserts an interest in enforcing a statutory provision that purportedly sets the Medicare payment rate for a particular pharmaceutical product on the basis of 95 percent of the average wholesale price of that product, and not on the basis of the Medicare payment rate for a competing pharmaceutical product. Like the plaintiff in *Tap Pharmaceuticals,* Amgen is asserting purely commercial interests in increasing its revenues and preventing loss of market share to its competitor. Like the plaintiff in *TAP Pharmaceuticals,* Amgen is neither a beneficiary of the Medicare statute nor a competitor of an entity that is regulated by that statute. . . Since its purely commercial interest in the sale of Aransep does not place it "in the same position as a member" of the beneficiary group or "a commercial competitor of such a member," Amgen, like the plaintiff in *TAP Pharmaceuticals*, cannot satisfy the prudential standing requirements imposed by the APA. [*Amgen*, 234 F. Supp. 2d at 24.]

Amgen also eschews the importance of the 1993 study regarding Epogen reimbursement conducted by HHS, but these are (again) disputed issues of fact. In any event, the 1993 HHS Report, as well as a follow-up report of HHS in late 1997, both documents state that "ESRD [end stage renal disease] facilities purchased EPO at a rate substantially less than the current Medicare reimbursement of $10 per 1,000 units," and that (even though Amgen repeatedly refused to provide sales and revenue figures) estimates of after-rebate costs to dialysis facilities were increasingly, and markedly, below the Medicare reimbursement rate. *See* Sobol Affidavit, ¶ J. When those after-rebate costs are compared to the AWP posted by Amgen for EPO, one can determine that AWP-based end-payors (third party payors or cash paying consumers) are paying markedly more for EPO, even if one flexibly interprets the AWP for EPO. The over-reimbursement of EPO for Amgen, and the consequent market share and profits to Amgen, were so large that the 1993 report detailed the ever-increasing profit margins of Amgen as one reason to revisit the Epogen reimbursement rate. In short, the allegations – not Amgen's factual denial of them – control in the 12(b)(6) context.

Although Amgen rehashes its argument that "Medicare does not reimburse Epogen based on AWP" this is simply not true. While a statutory rate exists for much of the Medicare products sold, not all Medicare reimbursement for (epogen) is based on that statutory rate structure. *See* all parts of 42 U.S.C. § 1395(rr)(b)(11)(D).

Amgen also raises a factual dispute that, given the statutory rate for some Medicare reimbursement, no other purchaser – public or private – could reasonably rely upon an AWP posted by Amgen as being a reflection of the true average wholesale price for the product. Amgen Mem. at 5 n.7. But a 12(b)(6) motion is not the place for factual disputes. Amgen's argument boils down to the claim that even if it fraudulently posted inflated AWPs for Epogen caused over-reimbursement in the private marketplace, that private marketplace could not reasonably rely upon what the average wholesale price is

because some Medicare reimbursements occurred at a statutory rate. A fact claim such as this is not appropriate in a 12(b)(6) context.

C. AstraZeneca

1. Review of AstraZeneca allegations

Plaintiffs allege that AstraZeneca L.P. ("AstraZeneca") has engaged in an ongoing deliberate scheme to inflate the Average Wholesale Price ("AWP") of its drugs. *See* ¶ 231. The effects of AstraZeneca's AWP manipulation have been significant. There are eighteen (18) drugs at issue for this Defendant that are identified in Appendix A to the AMCC and outlined by manufacturer, product name, generic name, NDC number and fraudulent AWP for varying years. Further, Appendix B references those specific employee benefit plan Plaintiffs that purchased any of the eighteen drugs manufactured by AstraZeneca.

In connection with its scheme to inflate AWPs, the U.S. Department of Justice ("DOJ") investigation into AstraZeneca resulted in an indictment in 2002. The indictment alleged that AstraZeneca (i) sold Zoladex® to a New Jersey physician and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey physician with materials showing how much more profit he could make by using Zoladex® rather than its competition, Lupron®. *See* ¶ 232.

AstraZeneca has controlled and manipulated the AWPs for its pharmaceutical products by directly marketing the AWP spread to physicians, providing large discounts to its providers, raising the AWP for Zoladex and, through its employees and agents, by providing millions of dollars worth of free samples of its drugs to physicians. *See* ¶¶ 241-42, 247. The free samples were intended by AstraZeneca to be used to offset the total cost associated with the purchase of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. *See* ¶ 247. Moreover, at least as to Zoladex, AstraZeneca sales representatives specifically told

medical providers that they could and should bill for the free samples. ¶ 247. Furthermore, AstraZeneca has produced documents to show that they have used the spread to induce Pharmacy Benefit Managers ("PBMs") to use AstraZeneca drugs on their formularies. *See* ¶ 236(b).

As set forth in the AMCC, AstraZeneca's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and Class members. *See* ¶ 249.

2. The AstraZeneca-specific arguments lack merit

a. Rule 9(b)

AstraZeneca's first Rule 9(b) specific argument is that the allegations regarding the use of AWPs in the PBM market lack specificity as to which drugs were involved. The answer is in ¶ 231, which identifies all AstraZeneca drugs at issue. AstraZeneca next claims there are no allegations as to how it marketed the spread to PBMs. In doing so, AstraZeneca ignores the general allegations as to the AWP scheme in the PBM context and ignores the specific example of the use of AWP reimbursement by Caremark:

Next, AstraZeneca labels as "inexcusable" the failure to list Plaintiffs' purchase price in a complaint. Not only is this not required, *infra* at III., and Consolidated Opposition at Section IV, but its never been required in this type of litigation. If this position is carried to its logical conclusion, Plaintiffs would have to have added to the 297 page Complaint, hundreds of pages of allegations as to purchase price information as there are six plaintiffs, with 317 drugs at issue, covering a six-year period of time or longer. The detail demanded now by defendants is what is "inexcusable," not the fact Rule 9(b) does not for good reason, require specification of damages in the AMCC.

Next, AstraZeneca complains that "plaintiffs do not even attempt to allege a 'fraudulent AWP' for any drug other than Zoladex." AstraZeneca Mem. at 2-3. Yet, in compliance with the Order, Plaintiffs identify fraudulent AWPs for every AstraZeneca drug in Appendix A.

b. Plaintiffs have standing

Of the 31 drugs identified in Appendix A, the union Plaintiffs have purchased 29 of these drugs. AstraZeneca, in a footnote, asserts that the claims in the case should be limited to Part B claims relating to Zoladex. This argument, however, conflates standing with 9(b). If 9(b) is not satisfied as to drugs other than Zoladex, the Plaintiffs who purchased virtually all of AstaZeneca's drugs do not lack standing, they just would have to plead with specificity. As to the Association plaintiffs, two specifically identify which

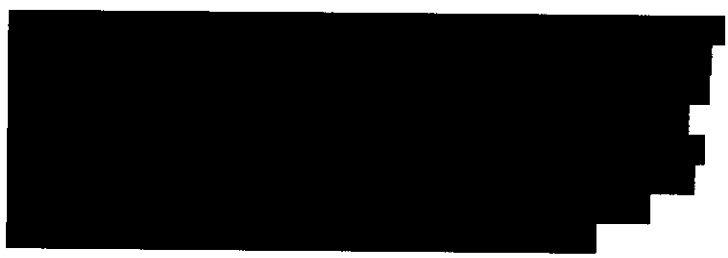
of their members purchased AstraZeneca drugs, so these Associations have standing. ¶¶ 34 and 36.

D. Aventis

1. Review of Behring allegations

Plaintiffs' AMCC alleges that three Aventis entities and Aventis Behring, LLC ("Behring") have engaged in an ongoing deliberate scheme to inflate the AWP of its drugs. Aventis Behring LLC has filed an individual Brief in Support of a Motion to Dismiss. The remaining entities identified as the "Aventis Group" in the AMCC have filed a separate 5 page individual brief. The one drug manufactured by Behring that is at issue in this case, Gammar, is identified in the AMCC, Appendix A by Manufacturer, Product Name, Generic Name, NDC number and fraudulent AWP for varying years.

In connection with its scheme to inflate AWPs, Behring has been investigated by numerous government agencies. *See* ¶ 251. These investigations have revealed inflated pricing implemented by Aventis Behring LLC (or its predecessor Centeon) for its Gammar® product line in order to keep provider and intermediary reimbursement levels competitive with those created by the inflated AWPs of other manufacturers. *See* ¶ 265. For example, a May 9, 1996 Aventis (Centeon) Interoffice Correspondence memo states:



Also, the Office of Inspector General of the Department of Health and Human Services revealed that the AWP for all immune globulin 5 mg. doses listed in the 1997 *Red Book* were inflated by an average spread of 32.21%. *See* ¶ 261. This conduct provided Aventis LLC Behring with the intended advantage over its competitors.

Moreover, in response to government subpoenas, Behring produced price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries that reveal Behring's consistent provision of drugs and other solutions to its customers at prices significantly below the published AWP. *See* ¶ 268.

As set forth in the AMCC, Behring's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class. *See* ¶ 270.

2. Review of Aventis Pharmaceutical allegations

The AMCC alleges that Aventis Pharmaceutical, Inc. and Hoechst Marion Rousell, Inc. (collectively "Aventis") have engaged in an ongoing deliberate scheme to inflate the AWPs. The drugs manufactured by Aventis that are at issue in this case are noted in Appendix A to the AMCC. Further, Appendix B to the AMCC references those specific Employee Benefit Plan Plaintiffs that purchased any of the drugs manufactured by Aventis.

Government investigations into Aventis' AWP pricing revealed inflated pricing implemented by Hoechst, continued by Aventis with respect to the injectable form of Anzemet®. *See* ¶ 264. The investigations uncovered substantial evidence that the fraudulent practices had resulted in excessive overpayments by consumer and third party payors that exceeded the actual cost of the drug to physicians. *Id.* Further, the purpose of the manipulation of the AWP was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

Nonetheless, Aventis routinely promoted differences in AWPs in marketing its products. *See* ¶ 257. Through its employees and agents, Aventis provided free samples of its drugs to providers, which were used to offset the total cost associated with purchases of its drugs, thereby increasing the spread while also concealing the actual cost of the drug from Plaintiffs and the Class. *See* ¶ 258.

As set forth in the AMCC, Aventis' scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class. *See* ¶ 270.

3. The Aventis and Behring-specific arguments lack merit

a. Behring

Aventis Behring argues that no plaintiff has purchased its drugs. What Behring fails to acknowledge is that plaintiffs have purchased drugs from its U.S. affiliate Aventis and have standing vis a vis the juridical link exception.

b. The Association Plaintiffs

Plaintiffs concede as to Aventis the Association Plaintiffs do not identify members who purchased an Aventis drug. Under the Order they would lack standing.

c. The claims involving Taxotene should not be dismissed

The AMCC identifies 13 drugs manufactured by Aventis and a purchaser for 12 out of the 13. For the reasons stated *infra* at III., D., in the circumstances of this case, Plaintiffs have standing as to all drugs in Appendix A.

d. Plaintiffs have satisfied 9(b) as to all Aventis drugs

As Aventis points out, the Order dismissed from the case "any and all claims involving drugs that Plaintiffs failed to identify both with respect to the name and the allegedly fraudulent published AWP for the drug." Aventis Mem. at 3. As noted above, Plaintiffs complied with the Order and for each Aventis drug identified the name of the drug and stated its fraudulent AWP. This pleading satisfies the Order.

Next, Aventis claims that the only allegation of fraud regarding Aventis are in ¶ 250 of the AMCC. In so doing, Aventis ignores the entire portion of the AMCC, which describes its participation in the AWP publishing system, the use of AWPs as a reimbursement benchmark in both Part B and non Part B markets, and the widespread abuse of AWP that is well-documented in Congressional and governmental

investigations. The Court in the Order already rejected all 9(b) arguments now advanced by Aventis, directed Plaintiffs as to what specifics were needed, and the specifics were supplied.

E. Baxter

1. Review of Baxter allegations

The 24 specific drugs of Baxter for which relief is sought in this case are set forth in Appendix A to the AMCC and are delineated by Product Name, Generic Name, NDC number and fraudulent AWP for varying years. Further, Appendix B to the AMCC references those specific Employee Benefit Plan Plaintiffs that purchased any of the 24 drugs manufactured by Baxter. The AMCC states that Baxter's AWP scheme is widespread and a government investigation has documented substantially inflated AWPs associated with Baxter pharmaceuticals. *See* ¶¶ 273-74. The OIG determined that in FY 1996, the Medicare-allowed amount for Baxter's Gammagard (immune globulin), was $42.21. The OIG further estimated that the actual wholesale price of this drug was $16.12 and the highest available wholesale price that the OIG was able to identify was $32.11. A document revealed in the Congressional Investigation titled "Confidential – Baxter Internal Use Only" acknowledges that: "Increasing AWPs was a large part of our negotiations with the large homecare companies." *See* ¶ 274. Baxter further admitted in internal documents that Homecare companies that reimburse based on AWP make a significantly higher margin. *Id.* Thus, Baxter's own documents demonstrate its active participation in the scheme to artificially inflate AWPs. *Id.*

In addition, the marketing and sales documents of Baxter frequently compared the AWP and the actual "cost" of their respective drugs, so that medical providers could easily see the different "return-to-practice" amounts available for different levels of purchase. ¶ 279.

For example, in a report published by DHHS, the DOJ documented at least forty-one (41) instances where the published AWPs for drugs manufactured by Baxter were substantially higher than the actual prices listed by wholesalers. ¶ 280. Baxter also provided physicians with free goods with the understanding that physicians would bill for those goods, in violation of federal law. *Id.* Billing for free goods was a way for physicians to obtain greater profit at the expense of the Class. ¶ 284. Baxter's fraudulent use of free goods aimed at increasing market share is evidenced by an internal memorandum from a Baxter contract administrator to certain field sales managers encouraging the distribution by United States mail or otherwise of free product to achieve overall price reduction:

> BAXTER: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction on Recombinate pricing. Please note that they want to continue to be invoiced at the $.81 price. They have requested that we send them free product every quarter calculated by looking at the number of units purchased in that quarter and the $.13 reduction in price . . . free product given to achieve overall price reduction." [*Id.*]

As set forth in the AMCC, Baxter's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by consumers and third-party payors. *See* ¶ 285.

2. The Baxter-specific arguments lack merit

a. Plaintiffs have standing

Baxter claims that Plaintiffs have standing as to only four of the Baxter drugs identified in the AMCC. This standing argument has been addressed elsewhere. *See infra* at III., D.

b. Baxter's multi-source drugs are properly in this case

Baxter claims that under Medicare's reimbursement scheme it cannot gain competitive advantage by implementing the AWP scheme. Baxter is wrong. Its own

documents reflect its use of the AWP spread to gain competitive advantage. ¶¶ 277-78. And, information supplied to the DOJ reveals a significant spread on generic or multi-source drugs which also reflects a competitive advantage. ¶¶ 283-84. And, Baxter has been providing free goods on multi-source drugs, thereby masking the true AWP. AMCC page 86 ¶ 13 [sic]. These facts belie the claim that multi-source drugs do not fit the AWP scheme alleged in the Complaint.

c. Baxter's 9(b) argument

Baxter's 9(b) argument is not Defendant-specific and merely reasserts arguments already made. However, it is important to note that Baxter is one of the Defendants that will not produce discovery. In these circumstances, as set forth in Plaintiffs' Memorandum in Support of Motion for Limited Discovery, where the information demanded is within its exclusive possession, the Court should engage in a *Becher*[12] analysis and allow discovery if the Court believes that 9(b) has not been satisfied. Nonetheless, and in the event that the Court remains unconvinced that Plaintiffs' allegations of the general scheme to defraud suffice, when coupled with the Baxter-specific section, the Court should permit Plaintiffs to obtain discovery into the average wholesale pricing spreads and other conduct associated with Defendants' marketing strategies. Such discovery, and an opportunity to amend, are supported, if not mandated, by *New England Data Servs., Inc. v. Becher*, 829 F.2d 286 (1st Cir. 1987).

Rather than simply dismissing a RICO complaint that a court finds is deficient in particularities, the First Circuit, in what has become known as the "*Becher* second determination," requires courts to determine whether the plaintiff has sufficiently outlined a general scheme to defraud under RICO (and used the wires and mails to further that scheme) such that additional discovery is warranted in order to bring the

[12] *New England Data Servs., Inc. v. Becher*, 829 F.2d 286 (1st Cir. 1987).

complaint into compliance with Rule 9(b). *Id.* at 290.[13] At a minimum, additional discovery and an opportunity to amend is warranted here because Plaintiffs have alleged the general scheme to defraud in great detail, citing to various governmental investigations and many specific drugs. Yet Plaintiffs cannot precisely define the scope of the case other than as already defined in the MCC without additional discovery from Baxter, because, in the words of this Court, the information is "peculiarly within the defendants' control." *Parke-Davis*, 147 F. Supp. 2d at 47 (quoting *Boston & Me. Corp. v. Hampton*, 987 F.2d 855, 866 (1st Cir. 1993)); *see also Becher*, 829 F.2d at 292. Baxter itself cites *Becher* and thus recognizes the appropriateness of such discovery.

d. Baxter role has been adequately defined

Baxter next claims that its role in the AWP scheme has not been adequately defined as to the state consumer protection, declaratory relief or civil conspiracy claims. Baxter cites to Rule 9(b), but to no authority applying 9(b) to a declaratory relief count for example.

As to its role, the AMCC adequately outlines how Baxter publishes phony AWPs, how those AWPs are used in the Part B and non Part B markets, and how Baxter's drugs reflect a significant difference between published AWP and the real price. The AWP provides an estimate of how this scheme affected Baxter's drug prices by setting forth estimated spreads for roughly 30 drugs, some with spreads of over 100%. No more detail is needed, particularly where at this stage the remaining information is largely within Baxter's control.

[13] Again, Plaintiffs do not believe that their MCC is deficient and have filed this motion in order to preserve their rights in the event that the Court disagrees. *See, e.g., Feinstein v. Resolution Trust Corp.*, 942 F.2d 34 (1st Cir. 1991) (suggesting that a plaintiff must ask the court, in a timely manner, for a limited period of discovery to bolster the complaint).

F. Bayer

1. Review of Bayer arguments

The AMCC alleges that Bayer Corporation ("Bayer") has knowingly participated and directed the ongoing scheme to artificially inflate the AWP of its drugs in order to increase the market share of its products. *See* ¶¶ 286-301. The AMCC states that Bayer has stated fraudulent AWPs for all or almost all of its drugs. *See* ¶ 286. The seven (7) specific drugs of Bayer for which relief is sought in this case are set forth in Appendix A to the AMCC and are delineated by Manufacturer, Product Name, Generic Name, NDC number and fraudulent AWP for varying years. *See* AMCC, Appendix A. Further, Appendix B to the AMCC references those specific Employee Benefit Plan Plaintiffs that purchased any of the ten drugs manufactured by Bayer. *See* AMCC, Appendix B.

In connection with its scheme to inflate AWPs, Bayer has been investigated by the Department of Justice, Department of Health and Human Services, Office of Inspector General, and the Commonwealth of Massachusetts. *See* ¶ 287. For example, in a report published by the Department of Health and Human Services ("DHHS"), the DOJ documented at least 10 instances where the published AWPs for various dosages of two drugs manufactured by Bayer were substantially higher than the actual prices listed by wholesalers. ¶ 293.

According to Bayer's own documents, the published AWPs for its drugs were higher than the actual prices provided to wholesalers. ¶ 296. In response to government subpoenas, Bayer produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. *Id.* A review of those price lists reveals that Bayer has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. *Id.*

Bayer has already agreed to settle claims by the United States Federal Government and with 47 states, arising from allegations identical to those set forth in the AMCC concerning AWP manipulation. *See* ¶ 287.

In addition to marketing the spread, Bayer has utilized other impermissible inducements to stimulate sales of its drugs. ¶ 297. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. *Id.* By utilizing "off-invoice" inducements, Bayer provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price. *Id.*

As set forth in the Complaint, Bayer's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class. *See* ¶ 299.

The Bayer-specific arguments lack merit

Bayer presents a contorted argument in the face of its acknowledgement that it has settled two major governmental probes relating in part to AWP issues. Bayer acknowledges, as it must, that Bayer was the first to settle investigations regarding inflated AWPs:

> The Bayer AWPs, at issue in the investigation, involved several of Bayer's biologic products such as Kogenate, Koate-HP, and Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases.
>
> The investigation further revealed that the practice in which Bayer selectively engaged, commonly referred to by drug manufacturers as "marketing the spread," also has the effect of discouraging market competition from manufacturers that do not inflate AWPs as a way of inducing doctors to purchase their products. ¶ 287.

Bayer also acknowledges, as it must, that earlier this year it settled the largest-ever Medicaid fraud settlement involving its drug pricing practices for Cipro and Adalat:

> Boston, MA. . . The nation's largest-ever Medicaid fraud settlements have been reached today with two American pharmaceutical companies, BAYER CORPORATION and GLAXOSMITHKLINE. The companies have agreed to pay settlement amounts totaling more than $344 million for their fraudulent conduct in a scheme commonly referred as "lick and stick," in which they sold re-labeled products to an HMO at deeply discounted prices, and then concealed and avoided their obligation to pay millions of dollars in additional rebates to the Medicaid program.
>
> . . . BAYER CORPORATION ("Bayer") and GLAXOSMITHKLINE ("GSK"), have each agreed to settle charges in connection with their efforts to evade praying rebates to state' Medicaid programs which were based on the lowest drug prices they were offering to an HMO.
>
> Today's agreement with BAYER calls for BAYER to pay a total of $257,200,000 to resolve criminal charges and civil liabilities in connection with the fraudulent drug pricing of its drugs, Cipro, an antibiotic, and Adalat CC, an extended release, anti-hypertensive.
>
> Additionally, BAYER has agreed to comply with the terms of an amended corporate integrity program designed to ensure that BAYER will accurately report its best price information to the government.

Bayer argues that its complicity in "lick and stick" fraudulent pricing practices for Cipro and Adalat "had nothing to do with AWP." This ignores, however, that the allegations of the AMCC control, and the AMCC alleges that Bayer's "lick and stick" fraud for Cipro not only had the consequence of avoiding best price regulations (by failing to disclose true, actual lower prices) but also had the effect of inflating the AWP for Cipro (because the published AWP did not reflect the disguised, "lick and stick" prices to favored purchasers). In short, Bayer has twice been caught with its hand in the cookie jar, once in 2001 and again in 2003, all for drug pricing fraud charges. Each of those probes involved apparent drug pricing practices, and each affected the manner in which public and private purchasers paid for Bayer drugs, all on the basis of the average wholesale price.

The entirety of Bayer's argument rests on the notion that its $257 million payment of penalties and fines for Cipro in 2003 "had nothing to do with AWP." Because the AMCC alleges otherwise (¶¶ 287-89), and those allegations control, the argument lacks merit.

2. Additional Bayer-specific arguments

Bayer's five page argument boils down to this: the only Bayer drug purchased by a Plaintiff is Cipro, thus Plaintiffs lack standing for other Bayer drugs identified in the complaint. This standing argument has been addressed elsewhere. *Infra* at III., C.

Bayer also argues that the facts in the AMCC deal with covered Part B drugs and that because Cipro is a noncovered drug it is somehow exempt from this case. However, as stated elsewhere, the Complaint is replete with allegations to how the AWP Scheme was implemented for covered as well as noncovered drugs. ¶¶ 168-178; *see also AWP Litig.*, 263 F. Supp. 2d at 179.

G. Boehringer Group

1. Review of Boehringer Group allegations

The AMCC alleges that Boehringer Ingleheim Corporation, Ben Venue Laboratories, Inc. and Bedford Laboratories ("The Boehringer Group") have knowingly participated and engaged in an organization-wide and deliberate scheme to artificially inflate AWPs in order to increase the market share of their products. *See* ¶ 302. The AMCC states that the Boehringer Group has stated fraudulent AWPs for all or almost all of its drugs. *Id.* The 11 specific drugs of The Boehringer Group for which relief is sought in this case are set forth in Appendix A to the AMCC and are delineated by Manufacturer, Product Name, Generic Name, NDC number and fraudulent AWP for varying years. *See* AMCC, Appendix A. Further, Appendix B to the AMCC references those specific Employee Benefit Plan Plaintiffs that purchased any of the 11 drugs manufactured by the Boehringer Group. *See* AMCC, Appendix B.

In a report published by the Department of Health and Human Services ("DHHS"), the Department of Justice ("DOJ") documented at least 32 instances where the published AWPs for various dosages of nine drugs manufactured by The Boehringer Group were substantially higher than the actual prices listed by wholesalers. *See* ¶ 311. Indeed, the Boehringer Group's published AWPs for the drugs documented by the DOJ were, in fact, higher than the actual prices provided to wholesalers. *See* ¶ 312. And its spreads between reported AWP and the real AWP were astounding, in some cases ranging between 1,000 and 6,000 percent. *See* ¶ 311. In response to government subpoenas, the Boehringer Group produced several price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. *Id.* A review of those price lists reveals that Bedford has consistently offered the above drugs and other solutions to its customers at prices significantly below the published AWP. ¶ 312.

As set forth in the AMCC, Boehringer's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class. *See* ¶ 313.

a. The standing argument

Plaintiffs purchased two drugs from the Boehringer group, Viramune and Levcovorin calcium. *See* ¶ 29. As to the remaining drugs, the standing argument has been addressed. *Infra* at III., D.

b. The Boehringer Group should not be dismissed because they were not served with the MCC in accordance with Local Rule 15.1

On September 9, 2002, Plaintiffs filed their Master Consolidated Complaint ("MCC") in the present action. According to Defendants Boehringer Ingelheim Corp., Ben Venue Laboratories, Inc. and Bedford Laboratories ("The Boehringer Group"), their "first notice that they had been added [to the present action] was upon receipt of the MCC

on September 17." Boehringer Group's Motion at p.3. Apparently, in the course of amending and consolidating numerous pending and transferred constituent complaints, Plaintiffs inadvertently (and regrettably) failed to satisfy the requirements of Massachusetts District Court Local Rule 15.1 as it relates to The Boehringer Croup. Because Plaintiffs' failure to satisfy Local Rule 15.1 neither prejudices The Boehringer Group, nor has delayed the present action, The Boehringer Group's motion should be denied.

Local Rule 15.1(b) states:

> A party moving to amend a pleading to add a new party shall serve, in the manner contemplated by Fed. R. Civ. P. 5(b), the motion to amend upon the proposed new party at least ten (10) days in advance of filing the motion, together with a separate document stating the date on which the motion will be filed. A motion to amend a pleading to add a new party shall be accompanied by a certificate stating that it has been served in advance on the new party as required by this rule.

Local Rule 15.1 "was adopted by the District Court of Massachusetts to comply with the Expense and Delay Reduction Plan of the District of Massachusetts, which sought to prevent the rampant late addition of parties 'that inevitably delays the case and generate[s] unnecessarily procedural litigation.'" *Nett ex rel Nett v. Belucci*, 269 F.3d 1, 3 (1st Cir. 2001) (deeming the plaintiffs' failure to comply with Local Rule 15.1 to be "harmless").

In the present action, identical to the "original" Defendants, The Boehringer Group has actively and aggressively defended against Plaintiffs' claims. In addition to filing motions to dismiss simultaneous with the other Defendants, The Boehringer Group has participated in scheduled hearings and discovery conferences. Noticeably absent from The Boehringer Group's motion is any suggestion that they – or the case itself – has suffered any prejudice[14] as a result of Plaintiffs' inadvertent noncompliance with Local

[14] *But see Ali v. Univ. of Mass. Med. Ctr.*, 140 F. Supp. 2d 107 (D. Mass. 2001). In *Ali*, the lone case cited by The Boehringer Group in support of their Local Rule 15.01 dismissal argument, the plaintiff failed

Rule 15.1. Simply stated, a dismissal of The Boehringer Group from the present action would neither serve the intended purpose of Local Rule 15.01 – nor the greater purpose of the AMCC. Accordingly, The Boehringer Group's motion should be denied.[15]

H. Braun

1. Review of Braun allegations

The AMCC alleges that Braun of America, Inc. ("Braun") has knowingly participated and engaged in an organization-wide and deliberate scheme to artificially inflate AWPs in order to increase the market share of its products. *See* ¶ 322. The AMCC states that Braun has stated fraudulent AWPs for all or almost all of its drugs. *Id.* The six (6) specific drugs of Braun for which relief is sought in this case are set forth in Appendix A. Further, Appendix B to the AMCC references those specific Employee Benefit Plan Plaintiffs that purchased any of the six drugs manufactured by Braun.

In connection with its scheme to inflate AWPs, Braun has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services ("DHHS"), the Attorney General for the State of Texas, and the Attorney General for the State of California. ¶ 315.

The purpose of Braun's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. ¶ 318. Braun understood, as reflected in a June 15, 1992 memorandum, that a higher AWP was "advantageous with payors who reimburse based on a cost plus arrangement." *Id.* Although Braun recognized that manipulating AWPs to meet its competitors was "scandalous," "unethical" and "fraudulent," Braun promptly proceeded to manipulate its AWPs and market the spread in an effort to match the competition. *See* ¶¶ 319-20.

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to comply with the Rule when seeking to amend his complaint a ***third*** time – over ***two years*** after he filed it.

[15] In the alternative, should the Court deem it necessary, Plaintiffs request the opportunity to belatedly comply with the requirements of Local Rule 15.1 as to The Boehringer Group.

A memorandum, created in October of 1997 reveals that Braun subsequently performed an analysis to "assure that McGaw AWPs are in line with Baxter/Abbott AWPs on competitive products." *See* ¶ 320. In fact, an October 17, 1997 Braun memorandum reveals that the company increased AWPs following a review of 200 drugs to "make them equivalent to both Baxter and Abbott." *Id.* Braun increased the AWPs of 29 drugs in 1996 for the same reason. *Id.* This is further evidenced by a report published by the DHHS (the "DHHS Report"), in which the DOJ documented at least 23 instances where the published AWPs for various dosages of three drugs manufactured by Braun were substantially higher than the actual prices listed by wholesalers. *See* ¶ 323. Furthermore, its own documents reveal that Braun used free goods, educational grants and other incentives to lower the effective price of its drugs without lowering the AWP. *See* ¶ 322.

As set forth in the Complaint, Braun's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class. *See* 326.

2. Braun-specific arguments lack merit

a. Plaintiffs' claims against B. Braun should not be dismissed because B. Braun America, Inc. shares an identity of interest with B. Braun Medical, Inc.

B. Braun America, Inc. should not be dismissed from this action because, as the parent company of B. Braun Medical, Inc., the original B. Braun Defendant named by Plaintiffs, B. Braun America shares an identity of interest with B. Braun Medical such that separate notice of the AMCC to B. Braun of America was not necessary. Rule 15(c)(3) of the Federal Rules of Civil Procedure provides that:

> An amendment of a pleading relates back to the date of the original pleading when . . . the amendment changes the party or the naming of the party against whom a claim is asserted if . . . the party to be brought in by amended (A) has received such notice of the institution of the action that the party will not be prejudiced in maintaining a defense on

> the merits and (B) knew or should have known that, but for a mistake concerning the identity of the proper party, the action would have been brought action the party.

Under the judicially-created identity-of-interest doctrine, "a new party may [be] added 'when the original and added parties are so closely related in business or other activities that it is fair to presume the added parties learned of the institution of the action shortly after it was commenced.'" *Moses v. Joint Frost, M/V*, C.A. No. 91-11247-WF, 1993 U.S. Dist. Lexis 5678, at *4-5 (D. Mass. Apr. 21, 1993) (quoting *Jimenez v. Toledo*, 604 F.2d 99, 102 (1st Cir. 1979)) (holding doctrine was satisfied where original party was alleged to have been "owned, operated, and controlled" by added party).[16] "The guideposts for evaluating whether two parties possess a sufficient identity of interest . . . are not well-defined." *Young v. Lepone*, 305 F.3d 1, 15 (1st Cir. 2002). "As to defendants, identity of interest typically means that parties are 'so closely related in their business operations or other activities that the institution of an action against one serves to provide notice of the litigation to the other.'" *Id.* at 14-15 (citation omitted). As alleged in the AMCC (¶ 69), after B. Braun of America acquired McGaw, Inc. in 1997, B. Braun of America became the parent company of, among others, B. Braun Medical, Inc. As the parent company of B. Braun Medical, B. Braun of America certainly did have (and in any event should have had) notice of Plaintiffs' Complaint against B. Braun Medical. [17]

In addition, "[t]he substitution of such [identity-of-interest] parties . . . is not significant when the change is merely formal and in no way alters the known facts and issues on which the action is based." *Young*, 305 F.3d at 15 (citation omitted). As the AMCC alleges, at least since its 1997 acquisition of McGaw, B. Braun of America has been "in the business of manufacturing and distributing prescription pharmaceuticals for

[16] Although the identity-of-interest doctrine is most typically used to determine if an amended complaint "relates back" to the filing of an original complaint for the purpose of determining the tolling of the statute of limitations, courts in this Circuit have used the doctrine to render decisions on issues such as the ones at issue here. *See, e.g., GSI Lumonics, Inc. v. Biodiscovery, Inc.*, 112 F. Supp. 2d 99, 103 (D. Mass. 2000) (using doctrine to determine first filed action).

[17] Defendants' argument that Plaintiffs' failure to serve B. Braun America, Inc. violates Rule 15.1 of this Court's Local Rules similarly fails. That rule requires service when a party seeks to add a "new party;" however, pursuant to the authority set forth above, B. Braun America, Inc. is not a new party.

distribution by Medicare Plan B providers nationwide." ¶ 69. These are precisely the same allegations Plaintiffs made regarding B. Braun Medical, Inc. — when Plaintiffs believed B. Braun Medical was the proper defendant to name. *See* MCC ¶¶ 79 and 80. Because B. Braun America, Inc. is the parent of B. Braun Medical, Inc., and because the allegations about the B. Braun entities in the MCC and the AMCC are substantially similar, B. Braun America cannot now claim that it was not on notice of the claims against it set forth in the AMCC.

b. Plaintiffs' claims against B. Braun America should not be dismissed because the Associational Plaintiffs have standing and because this Court has not required Plaintiffs to plead that *all* Plaintiffs purchased drugs from each Defendant

The allegations in the AMCC regarding Plaintiffs' purchases of B. Braun drugs are likewise sufficient. B. Braun first claims that the Associational Plaintiffs have failed to allege the purchase of any drug from B. Braun themselves or through their members. However, for the reasons set forth in the Plaintiffs' Opposition to Defendants' Combined Motion to Dismiss (which is incorporated herein by reference), B. Braun's claim fails.

B. Braun also claims that the claims of the Board of Trustees of Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund and the Man-U Service Contract Trust Fund must be dismissed because neither Plaintiff has allegedly purchased any drugs from manufactured by B. Braun. However, this Court's May 13, 2003 Order did ***not*** require that ***every*** Plaintiff purchase a drug from ***every*** Defendant. Instead, that Order dismissed "certain companies from which ***no plaintiff*** claims to have purchased a drug with an inflated AWP." Memorandum and Order (May 13, 2003), at 3 (emphasis added). The Court was only concerned with Plaintiffs' allegations that "a named plaintiff who has purchased one drug from one of the defendants can serve as a class representative . . . in a class of all persons who made purchases of covered drugs from any defendant, even those companies against which no named plaintiff claims to have

made a purchase." *Id.* at 41. The Court specifically reserved the issue raised by B. Braun, stating that:

> For present purposes, however, I decline defendants' invitation to determine whether a plaintiff who purchased one drug from a given company has standing to represent a class of others who purchased a different drug or drugs from the same company. Those allegations fit better into the juridical linkage claim, and the issue will be decided at a later stage in the litigation.

Id. at 43. The case cited by the Court, *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999), makes clear that the Court believed this "later stage" of litigation should be at class certification and, in any event, is clearly improper for a motion to dismiss.

In addition, B. Braun asserts that all claims by any Plaintiff involving purchases outside of the Medicare Part B context must be dismissed because Plaintiffs have purportedly not sufficiently alleged causation. But this is just another way of restating the argument in Defendants' Combined Motion to Dismiss that Plaintiffs lack standing to pursue their claims. Therefore, for the reasons set forth in Plaintiffs' Opposition to Defendants' Combined Motion to Dismiss, B. Braun's arguments must be rejected. Further, B. Braun's argument is merely a backdoor attempt to circumvent the law of this Court – that a RICO plaintiff is ***not*** required to plead detrimental reliance. *See Sebago, Inc. v. Beazer East, Inc.*, 18 F. Supp. 2d 70, 82 (D. Mass. 1998) (finding "the line of cases that decline to read into RICO mail fraud cases a requirement of actual, detrimental reliance are most faithful to the [RICO] statute and, in any event, most persuasive.").

c. The proper scope of BBA drugs in this Complaint

Where that leaves Braun is in the same position as other Defendants. Plaintiffs have purchased two of the six drugs identified in Appendix A. Thus, Braun makes the same standing argument addressed elsewhere. And, Braun then argues that any claim outside the Part B context must be dismissed. Again, this argument has been addressed elsewhere. *See infra* at III., C; and Consolidated Opposition at Section VIII., B. In a new

twist Braun argues that no Plaintiff has alleged that it purchased a drug from Braun based on an AWP, but this is certainly a strained reading of the AMCC which clearly has at its core the fact that AWP is the reimbursement benchmark for Part B and private reimbursements and was for the Plaintiffs. *See, e.g.*, ¶ 168. And it ignores ¶ 139 which alleges that Plaintiffs paid for drugs based on the inflated AWPs reported by Defendants.

d. Braun's "median price" argument does not defeat the allegations of the Complaint

Braun claims that because Medicare reimburses at the median AWP it is immune from suit. Braun is wrong.

First, Braun has admitted that the AWP practice is "scandalous," "unethical" and "fraudulent," which would not be the case if it made no difference to actual reimbursement. ¶ 319. Braun reported AWPs that are 601, 500, 660, 757, 1063, 1260 percent greater than the real AWP. Its nonsensical to conclude that such inflated reporting does not effect the median.

Second, the median is not always used as the reimbursement price point. *See* Consolidated Opposition Mem. at Section VIII.

Third, Braun repeats the argument that multi-source drugs do not fit the paradigm in the Complaint. However, with spreads ranging from 600% to 1260%, Braun's drugs are within the paradigm.

I. Bristol Meyers' Specific Arguments

1. Review of Bristol Meyers allegations

The AMCC states that BMS has stated fraudulent AWPs for all or almost all of its drugs. The twenty (20) specific drugs of BMS for which relief is sought in this case are set forth in Appendix A.

The AMCC states that the investigations of numerous state and federal agencies have confirmed that BMS engaged in an ongoing deliberate scheme to inflate AWPs. *See* ¶ 329. For example, by letter dated February 27, 2001 to BMS, Rep. Stark outlined

numerous examples of illegal practices by BMS. *See* ¶ 329. Referring to a letter from Denis Kaszuba, a senior pricing analyst at BMS to Medispan, dated August 10, 1992 (BMSAWP/0011247), Rep. Stark noted:

> Bristol has control over the AWPs, DPs, and WACs published for its drugs and directs national publishers to change their prices. Bristol directed a national publisher of drug prices to increase all of Bristol's AWPs for oncology drugs by multiplying Bristol's supplied direct prices by a 25% factor rather than the previous 20.5% factor . . . The increase in the AWP created a spread that, in itself, provided a financial kickback to oncologists for prescribing Bristol's cancer drugs.

In the same letter, Rep. Stark noted:

> The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

¶¶ 329-30.

Internal documents of BMS clearly indicate that not only did BMS have direct control over the spread between its states wholesale price and the published AWP, but that it was well aware that providers and other purchasers of its drugs were using the spread to determine whether to purchase its drugs. ¶¶ 332-33. Indeed, BMS created AWP competitor analyses that tracked the AWPs of its competitors' relevant drugs, and used that data internally to propose suggested AWPs for BMS drugs. ¶ 334. This is further evidenced by a report published by the DHHS (the "DHHS Report"), in which the DOJ documented numerous instances where the published AWPs for various dosages of five (5) drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers. ¶ 336.

As part of its scheme the BMS Group also used free drugs and other goods to encourage participation by physicians. ¶ 340. As set forth in the AMCC, the BMS Group's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class. *See* ¶ 341.

2. The Bristol Meyers-specific allegations lack merit

Bristol's arguments with respect to the PBMs has been addressed elsewhere, as has its free goods argument.

Bristol now raises a statute of limitations argument. This fails for two reasons. First, it is not Bristol-specific and hence should have been in the consolidated opposition. Second, it was raised and rejected in the earlier briefing. *See AWP*, 263 F. Supp. 2d at 194. If the Court needs additional briefing on this issue, Plaintiffs will respond at the Court's direction.

J. Dey

1. Review of Dey allegations

The AMCC alleges that Dey Incorporated ("Dey") has knowingly participated and engaged in an organization-wide and deliberate scheme to artificially inflate AWPs in order to increase the market share of its products. ¶ 349. The six specific drugs of Dey for which relief is sought in this case are set forth in Appendix A to the AMCC and Appendix B references those specific Employee Benefit Plan Plaintiffs that purchased Dey drugs.

Investigations conducted by the federal government in connection with Dey's manipulation of the AWPs, confirmed that Dey has engaged in a deliberate scheme to inflate the published AWPs for many of its drugs. *See* ¶¶ 350-51. For instance, Dey's spread for albuterol sulfate, a drug that constituted 37 % of Dey's income in 1998, drastically increased between 1992 and 1998. ¶ 351. In 1992, Dey's *Red Book* AWP for

albuterol sulfate (.083% concentration, 3 ml) was $32.30. *Id.* McKesson's wholesale price for the drug was $25.45 (a spread of $ 6.85 or 27%). *Id.* By 1998, Dey's *Red Book* AWP for the same concentration/dose of albuterol sulfate had barely slipped to $30.25, while McKesson's wholesale price had plummeted to $10.00 (a spread of $20.25 or 202%). *Id.*

In addition to the federal government's discovery of Dey's scheme to inflate the AWPs, both the Attorneys General of Texas and West Virginia recently uncovered that due to over inflated AWPs, both state's Medicaid Programs have been defrauded by Dey for millions of dollars. *See* ¶ 353.

Dey's documents consistently demonstrate that the published AWP of its drugs far exceeds the actual price of those drugs. Many of the resulting spreads for its drugs are well in excess of 100%. *See* ¶ 360.

As set forth in the Complaint, Dey's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class. *See* ¶ 363.

2. The Dey-specific allegations lack merit

Despite the bombast in Dey's separate memorandum, the AMCC provides specifics as to Dey's manipulation of the average wholesale price in a manner consistent with this Court's ruling and the requirements of Rule 9(b). The AMCC identifies five Dey drugs subject to the allegations of the AMCC; provides various examples by which those drugs have been inflated (including estimates of percentage overcharges); provides examples of Dey control over the AWP; provides specific examples of "spread shopping" by Dey; provides examples of the DOJ documented AWP inflation by Dey, and; provides detailed examples of Dey's use of wholesaler pricing proposals to market the spread. Dey has adequate notice of the claims against it. ¶¶ 354-60.

Dey complains that there is no single fact that alleges Dey is responsible for fraud. Dey Mem. at 3. However, Plaintiffs cite to internal Dey documents regarding "spread shopping" (¶ 355) and to the enormous spread on Dey's products, 488, 355, 239, 177 percent overcharges. These allegations when combined with the general allegations, satisfy Rule 9(b), and create an inference of Dey's participation in the AWP scheme.

Dey complains that the excerpted pricing proposal incorporated in the AMCC is fabricated. The excerpt is used in the AMCC as an example of how Dey's own documents showed the AWP is vastly larger than the actual prices for Dey products. While the "% spread" column including in the AMCC does not appear on the original document (see Dey, Exhibit 1), the ***math*** for the "% spread" column ***is accurate***. The AMCC table no. 1 for Dey is not "manufactured evidence." In fact, as Dey's own document confirms, for each of the drugs listed in the table, Dey's representations regarding the AWP bear no relationship to wholesale acquisition costs, suggested sale prices or actual transaction price.[18]

K. Fujisawa

1. Review of Fujisawa allegations

The 16 specific drugs of Fujisawa for which relief is sought in this case are set forth in Appendix A and Appendix B references those specific employee benefit plan plaintiffs that purchased any of the 16 drugs manufactured by Fujisawa.

In connection with its scheme to inflate AWPs, Fujisawa has been investigated by the United States Department of Justice ("DOJ"), the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California. ¶ 365. In the course of its investigation, the DOJ documented at least 35 instances where the published AWPs for

[18] The AMCC Table no. 1 for Dey does not purport to be the actual version of the table as it exists in Dey's own records. The only difference between the table and the AMCC and the chart in Dey's own document is the mathematical calculation of the spread between AWP and suggested sale price (although the original document does provide percentage spreads between WAC and sales price). There is nothing "manufactured" about the allegations in the AMCC.

various dosages of six drugs manufactured by Fujisawa were substantially higher than the actual prices listed by wholesalers. ¶ 371. Supporting the government's findings and in response to government subpoenas, Fujisawa produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. ¶ 372. A review of the price lists reveals that Fujisawa has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. *Id.*

As set forth in the AMCC, Fujisawa's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

2. The Fujisawa-specific arguments lack merit

a. The AMCC adequately alleges fraud

Fujisawa asserts that the AMCC is "entirely devoid" of any explanation of what constitutes the fraud. This, of course, ignores the Court's recap of the AWP scheme in the order. *AWP*, 263 F. Supp. 2d at 178-80. And the Complaint adequately alleges that the "fraud" consisting of the publishing of phony AWPs that bear little relationship to any actual AWP. ¶¶ 3-5, 138-39, 142-90. Fujisawa will not have to guess as to what is at issue in the case. Fujisawa Mem. at 2.

Fujisawa repeats the refrain that Plaintiffs were required to identify the price for each of its drugs. This is not required, as explained elsewhere. *See infra* at III., B. Plaintiffs have alleged that they purchased the drugs and that they overpaid; this is enough.

Nothing in the Order required the detail now demanded by Fujisawa.

b. Standing

Fujisawa asserts the same standing argument. Plaintiffs have purchased four of the drugs in the AMCC. *See infra* at III., D.

c. Fabricated AWPs

Fujisawa launches its specific opposition with the factual accusation that the Plaintiffs "have simply fabricated alleged AWPs" with respect to eight multi-source drugs which, Fujisawa claims, Plaintiffs "allege were published in the 1999, 2000 and 2001 Red Books. . ." Fujisawa Me. at 3. Fujisawa then submits extraneous evidence (in the form of Red Book pages) in an effort to claim that the AWPs for those years, for those drugs, do not appear to be listed. *Id.*, Exhibit A. Fujusawa then ends with the flourish: "The only fraud here in the Plaintiffs' false assertion of their fabricated AWPs." The argument lacks merit and the invective is uncalled for.

First, Fujisawa's argument ignores the fact that the AWPs listed for these either multi-source drugs, ***do***, in fact, appear in the 1998 Red Book. Second, nowhere does the AMCC allege that AWPs are ***only*** published in the Red Book; it alleges they are published in multiple locations ***including*** the Red Book. ¶ 135. The AMCC at Appendix A, sets forth allegations of fact (which cannot be disputed here) that the AWPs set forth in it have been published; that fact allegation controls for these purposes. Moreover, these AWPs – and inflated spreads associated with them by Fujisawa – have themselves been the subject of scrutiny by public investigators. *See, e.g., Program Memorandum*, DHHS, PMREB. AB-00-86 (Sept. 8, 2000) (listing inflated AWPs for Fujisawa generics, including acyclovir, dexanethasone, gentamicin, pentamidine, vancomycin and doxorubicin).[19] (Ex. K to Sobol Affidavit.)

[19] Plaintiffs are aware that in late 1998, American Pharmaceutical Partners, Inc. acquired certain rights with respect to certain multi-source products of Fujisawa. Indeed the Red Book pages attached by Fujisawa set forth the AWPs for these generic products (see the "APP" listings next to those drugs). Plaintiffs' information and public reports shows AWPs for these multi-source drugs under the Fujisawa name. If the issues Fujisawa raises are associated with some underlying confusion also relating to the corporate transactions with APP, those issues certainly could have been resolved had Fujisawa attempted to narrow the issues in accordance with Local Rule 7.1(a)(2) (requiring counsel to confer in a good-faith attempt to narrow issues). Instead, Fujisawa counsel simply resorted to accusations of fabrication.

L. GSK Group

1. Review of GlaxoSmithKline allegations

In the AMCC Plaintiffs allege specific facts against GlaxoSmithKline, Inc. and SmithKline Beecham, PLC ("The GSK Group" or "GSK"). Specifically, the AMCC states several federal and state investigations revealed that The GSK Group engages in a deliberate and ongoing scheme to inflate AWP. *See* ¶ 378. The thirty-two (32) specific drugs of GSK for which relief is sought in this case are set forth in Appendix A to the AMCC, and Appendix B to the AMCC references those specific Employee Benefit Plan Plaintiffs that purchased any of the 32 drugs manufactured by GSK.

The AMCC charges that GSK has direct control over the "markups" in the distribution chain for its products, and as a result of that control, has the ability to set the published AWP. ¶ 381. GSK's own documents state, [redacted] ¶ 382. Elsewhere in the same document GSK acknowledges: [redacted] *Id.*

The purpose of GSK's AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. ¶¶ 383, 387. GSK's scheme has resulted in a system where drugs are administered based upon a profit incentive to physicians and other intermediaries and which results in an incentive to prescribe more expensive, rather than cheaper, drugs. *Id.* In order to maximize its spread, GSK increased the AWP for its Zofran® product but attempted to conceal that fact by electing to increase its AWP and provide rebates and also to include small actual price increases. ¶ 389. In describing the reason for an increase in the actual selling price, an internal GSK document states:

> The recommended multi-tiered modification to current promotion, should also provide an immediate resultant impact to weekly unit sales without being easily intelligible by SKB as to the means by which this was achieved. Thus, providing additional time before a competitive response would be delivered. [*Id.*]

In fact, the government has uncovered substantial evidence that the GSK Group's fraudulent practices are widespread and not merely limited to Zofran and Kytril as GSK's brief would indicate. In a report published by the Department of Health and Human Services, the Department of Justice documented at least five AWPs inflated by GSK entities in 2001.

As further set forth in the AMCC, GSK's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial incentives to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

2. The GSK-specific arguments lack merit

a. The claims should not be limited to Zofran and Kytril

GSK claims that the claims should only proceed as to Kytril and Zofran. It cites to the Order as authority for this proposition, but as explained elsewhere Plaintiffs complied with all three requirements of the Order.

GSK claims that stating in Appendix A the AWP for each drug is not enough. This argument ignores the Order and ignores the fact that Plaintiffs have set forth a detailed overview of the AWP scheme, have detailed the scheme as to certain drugs and have identified the AWP at issue as to all drugs. This is enough, particularly when the information is hidden by GSK. If GSK demands more Plaintiffs should be entitled to *Becher* discovery.

b. The claims are not limited to Medicare Part B

GSK states "as stated in the consolidated memo" all non-Medicare allegations should be dismissed. *See* Consolidated Mem. at IV., C.-E. for Plaintiffs' response.

But GSK is also wrong as to a few of the points it makes. GSK claims there are no allegations as to which drugs are at issue; all Appendix A drugs are at issue. GSK claims there is no allegation as to which PBMs are involved. The AMCC identifies the PBMs. ¶ 170. And, GSK is wrong when it states there is not a single allegation as to how the spreads are marketed. The AMCC explains how AWPs are used by PBMs to increase the price of drugs to payors. ¶¶ 171-78.

M. Hoffman-La Roche

1. Review of Hoffman-LaRoche allegations

In the AMCC Plaintiffs allege specific facts against Hoffman-LaRoche, Inc. ("Hoffman"). Specifically, the AMCC states several federal and state investigations revealed that Hoffman engages in an organization-wide and deliberate scheme to inflate AWPs. Hoffman has stated fraudulent AWPs for all or almost all of its drugs, including Kytril and CellCept. ¶ 417. The three specific drugs of Hoffman for which relief is sought in this case are set forth in Appendix A to the AMCC, and Appendix B to the AMCC references those specific Employee Benefit Plan Plaintiffs that purchased any of the sixteen drugs manufactured by Hoffman.

The AMCC states that Hoffman has controlled and set the AWPs for its pharmaceutical products through its communications with the industry and have published higher AWPs for Kytril and CellCept than the actual prices for wholesalers. *See* ¶ 418. Further, in addition to marketing the AWP spread, Hoffman has used impermissible inducements to stimulate sales of its drugs, which are designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. ¶ 420.

As set forth in the AMCC, Hoffman's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of "off

invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class. *See* ¶ 421.

2. The Hoffman-specific arguments lack merit

a. Cellcept TX

Hoffman raises a standing argument previously addressed.

b. Failure to state a fraudulent AWP

Plaintiffs in Appendix A, as required by the Order, identify the AWP for Hoffman. For the reasons amply stated throughout, this is sufficient. Further, Hoffman is another Defendant not subject to discovery and if more is required, *Becher* discovery is appropriate.

c. All of Hoffman's remaining arguments are addressed

Hoffman's remaining arguments as to standing have been covered in other briefs and any ruling will cover these repetitive arguments.

N. Immunex

1. Review of Immunex allegations

In the AMCC, Plaintiffs allege specific facts against Immunex Corporation ("Immunex"). Specifically, the AMCC states several federal and state investigations revealed that Immunex engages in an organization-wide and deliberate scheme to inflate AWPs. *See* ¶ 422. Hoffman has stated fraudulent AWPs for all or almost all of its drugs. *Id.* The five specific drugs of Immunex for which relief is sought in this case are set forth in Appendix A to the AMCC and delineated by Manufacturer, Brand Name, Generic Name, NDC number, and fraudulent AWP for varying years. *See* AMCC, Appendix A.

In 2000, government investigations revealed that Immunex has deliberately attempted to hide its participation in the scheme to inflate AWPs. Immunex's own internal documents reveal that it has controlled the AWP for all of its products. For example, a January 12, 1996 letter from *Red Book* to Immunex that states, "This letter is

a confirmation letter that we have received your latest AWP price changes in our system." ¶ 426.

The purpose of Immunex's manipulation was to increase the spread in order to maximize profit to providers at the expense of Plaintiffs and the Class. In fact, in a conscious effort to increase the spread, Immunex changed its AWP and marketing practices by establishing a "Reimbursement Hotline" for a number of its products and providing free samples of its drugs to customers. ¶¶ 429-30.

In a report published by the Department of Health and Human Services ("DHHS"), the Department of Justice documented at least seven instances where the published AWPs for various dosages of two drugs manufactured by Immunex, Leucovorin Calcium and Methotrexate Sodium, were substantially higher than the actual prices listed by wholesalers. ¶ 431. Another report by the DHHS undertook an analysis of the 20 drug codes that represented the largest dollar outlays to the Medicare Program and compared Medicare's payments with the prices available to the physician and supplier communities and determined that Immunex pricing for Novantrone (mitoxantrone hydrochlorider) resulted in a 21.36% spread. ¶ 432.

As set forth in the AMCC, Immunex's scheme has resulted in excessive overpayments by Plaintiffs and the Class, and in some cases, co-payments that exceed the actual cost of the drug to physicians.

2. The Immunex-specific arguments lack merit

a. Standing

Plaintiffs have identified two purchasers of Immunex drugs identified in the complaint. There are five identified in the AMCC. Immunex thus raises the same standing argument addressed elsewhere.

Immunex claims it is not sufficient to simply identify the published AWPs from 1997-2002. Plaintiffs, according to Immunex, must establish facts. In making this

argument, which unfortunately by this point has been repeated in at least 15 briefs, Immunex ignores the Order and its context. Immunex and the other Defendants made the same 9(b) arguments as to the MCC. The Court considered those arguments and set forth what further material was required in the AMCC. Plaintiffs complied with the Order.

Immunex's argument ignores, as do related arguments, the general allegations outlining the AWP scheme, the specific allegations as to Immunex and the logical inferences to be drawn as to other drugs. Those logical inferences are particularly appropriate where the information is within Immunex's exclusive possession.

O. Novartis

1. Review of Novartis allegations

In the AMCC Plaintiffs allege specific facts against Novartis Pharmaceutical Corporation ("Novartis"). Specifically, the AMCC states, and several governmental investigations have confirmed, that Novartis created and implemented a fraudulent scheme to artificially elevate prices charged for 26 specific drugs and substantially increased the sales volume and market share of those drugs at those elevated prices. The 26 drugs, for which Plaintiff alleges Novartis has stated fraudulent AWPs, have been set forth in Appendix A to the AMCC, and are delineated by Manufacturer, Product Name, Generic Name, NDC number and fraudulent AWP for varying years. Appendix B to the AMCC references those specific Employee Benefit Plan Plaintiffs that purchased any of the 26 drugs manufactured by Novartis.

The AMCC further alleges that Novartis has controlled and set the AWPs for its pharmaceutical products through direct communications with the industry for the purpose of manipulating the spread in order to maximize profit to its providers and other intermediaries at the expense of Plaintiffs and Class members.

In connection with its scheme to inflate AWPs, the OIG has investigated Novartis. *See* ¶ 447. The OIG published a report for the Department of Health and Human

Services in 2000 documenting Novartis' inflated AWP for Aredia, its brand of pamidronate disodium. *Id.*

As set forth in the AMCC, Novartis' scheme has resulted in excessive overpayments by consumer and third party payors, and in some cases, co-payments that exceed the actual cost of the drug to physicians.

2. The Novartis-specific arguments lack merit

a. Standing

The standing argument has been addressed elsewhere.

b. 9(b)

All of the 9(b) arguments have been addressed elsewhere.

c. NPC's statutory arguments are addressed in the Consolidated Memorandum

Novartis asserts a series of arguments as to the specifics of various state consumer protection laws. This is not a Defendant-specific memoranda but is an issue applicable to all Defendants. To the extent these issues were properly raised in Defendants' consolidated opposition, they are addressed in Plaintiffs' consolidated memorandum. *See* VII.

d. State law connection

Again Novartis' argument as to the lack of a connection between plaintiffs and a state consumer law is not defendant-specific and should have been in the Consolidated Memorandum. Plaintiffs respectfully submit that the choice of law issues raised in this section of Novartis' brief are better addressed at a later date when choice law issues arise, such as class certification. For example, examining the argument that Illinois requires "in person status" or that the "deceptive acts have some connection to Illinois," some of the Defendants are based in Illinois. At the appropriate time, Plaintiffs will argue that since Abbott, for example, is based in Illinois, a nationwide class is appropriate under Illinois law and that law applies to all. The same is true for those headquartered in New York.

This choice of law/class issue is respectfully best addressed at a later stage and not in the two pages devoted to it.

P. Pfizer

1. Review of Pfizer's allegations

In the AMCC Plaintiffs allege specific facts against Pfizer Inc. ("Pfizer"). Specifically, the AMCC alleges, and at least one government investigation has confirmed, that Pfizer created and implemented a fraudulent scheme to artificially elevate prices charged for 20 specific drugs and substantially increased the sales volume and market share of those drugs at those elevated prices. The 20 drugs, for which Plaintiff alleges Pfizer has stated fraudulent AWPs, have been set forth in Appendix A to the AMCC, and Appendix B to the AMCC references those specific Employee Benefit Plan Plaintiffs that purchased any of the twenty drugs manufactured by Pfizer.

The AMCC states with particularity specifics regarding Pfizer's deliberate scheme to inflate AWPs. Specifically, the AMCC alleges that in January 2002, Pfizer secretly increased the AWP/WAC spread to 25% for ***all*** of its brand name drugs and by doing so, Pfizer knew that the effect of these new listings would be to increase reimbursement payments by end payors by amounts that would be greater than actual transaction costs for other participants in the distribution chain and that the posted AWPs for many of their brand name drugs would become more misrepresentative of actual average wholesale prices. ¶¶ 453-54.

Further, Plaintiffs allege in the AMCC specific facts regarding the state and federal investigations regarding Pfizer's illegal practices with respect to Lipitor and the OIG findings that Pfizer has been providing unrestricted educational grants and rebates that were in fact discounts off the purchase price of Lipitor. ¶ 455. The provision of educational grants and rebates on Lipitor also had the effect of inflating the reported AWP. ¶ 456.

As set forth in the AMCC, Pfizer's scheme has resulted in excessive overpayments by consumer and third party payors, and in some cases, co-payments that exceed the actual cost of the drug to physicians.

2. The Pfizer-specific arguments lack merit

a. The AMCC states a claim against Pfizer

Pfizer claims that the AMCC must specify the fraudulent statements that plaintiff contends were fraudulent. The AMCC does so; it specifies in Appendix A the phony AWPs for Pfizer. Pfizer claims that the AMCC must identify the speaker of the statement. The AMCC identifies Pfizer as the company that transmits its AWPs to the publisher. So that element is satisfied. Pfizer next demands that the AMCC must identify where and when the statements were made. The AMCC does that, alleging that Pfizer caused to be published AWPs that were phony during the period of at least 1997 to 2002. And Pfizer demands that the AMCC state why the statements were fraudulent. The AMCC does so as well; it identifies why the published AWPs are a fictitious number. By Pfizer's own construction of Rule 9(b), the AMCC passes muster.

Pfizer then claims that Plaintiffs did not comply with the Order, because Plaintiff did not "clearly and concisely allege a fraudulent AWP for any Pfizer drug." Appendix A does just that. And again, Pfizer ignores the backdrop of Appendix A is the detailed general allegations as to the AWP scheme, pursuant to which all Defendants participants.

To the extent more is required, discovery of Pfzier should be permitted pursuant to *Becher*.

Q. Pharmacia Group

1. Review of Pharmacia's allegations

There is little question that the AMCC alleges Pharmacia's involvement in the AWP scheme. In internal documents, Pharmacia notes that at one time AWPs were the

actual selling price, but that process changed in the 1980s. ¶ 460. This change resulted in Pharmacia marketing AWPs that differed in a "staggering" fashion with the true price:

In a letter dated October 3, 2000 to Pharmacia (with accompanying exhibits), Representative Stark addressed the Pharmacia Group's illegal practices:

> The manipulated disparities between your company's reported AWPs and DPs are staggering. For example, in 1997, Pharmacia & Upjohn reported an AWP of $946.94 for 200 mg. of Adriamycin PFS while offering to sell it to American Oncology Resources (AOR) for $168.00 and to Comprehensive Cancer Center for $152.00 (Composite Exhibit "1"). Your company then aggressively marketed its cancer drugs to health care providers by touting financial inducements and other types of incentives. Pharmacia & Upjohn created and marketed the financial inducements for the express purpose of influencing the professional judgment of doctors and other health care providers in order to increase the company's market share.
>
> * * *
>
> Pharmacia & Upjohn's own internal documents . . . reveal that the company abused its position as a drug innovator in an initial *Phase III* FDA clinical trial for a cancer drug used to treat lymphoma (Composite Exhibit "2") (emphasis in original).
>
> ". . . Clinical Research Trials
>
> > Initial Phase III Protocol trial for "Oral Idamycin" in lymphomas. This trial will offer AOR $1.1M [million] in additional revenues. Two hundred twenty-five (225) patients at $5,000 per patient . . . (emphasis added by Rep. Stark)
> >
> > The above . . . items are contingent on the signing of the AOR Disease Management Partner Program. AOR's exclusive compliance to the purchase of the products listed in the contract product attachment is also necessary for the above items to be in effect."
>
> The linking of doctor participation in FDA clinical drug trials to their purchase and administration of profit-generating oncology drugs is entirely inconsistent with the objective scientific testing that is essential to the integrity of the trial.
>
> * * *

It is clear that Pharmacia & Upjohn targeted health care providers, who might be potential purchasers, by creating and then touting the windfall profits arising from the price manipulation. For example, Pharmacia & Upjohn routinely reported inflated average wholesale prices for its cancer drug Bleomycin, 15u, as well as direct prices. The actual prices paid by industry insiders was in many years less than half of what Pharmacia & Upjohn represented. Pharmacia & Upjohn reported that the average wholesale price for Bleomycin, 15u, rose from $292.43 to $309.98, while the price charged to industry insiders fell by $43.15 (Composite Exhibit "4").

* * *

Pharmacia & Upjohn reported price increases in October 1997 with full knowledge that the true prices of the drugs were falling. For example, Composite Exhibit "7" reveals that Pharmacia & Upjohn voluntarily lowered its price of Adriamycin PFS 200 mg to $152.00 while reporting an AWP of $946.94:

> "Dear Willie,
>
> > A (VPR) Voluntary Price Reduction will become effective May 9, 1997. The wholesalers have been notified, however it may take two weeks to complete the transition . . ."

Additionally, internal Pharmacia & Upjohn documents secured through the Congressional investigations show that Pharmacia & Upjohn also utilized a large array of other inducements to stimulate product sales. These inducements, including "educational grants" and free goods, were designed to result in a lower net cost to the purchaser while concealing the actual price beneath a high invoice price. Through these means, drug purchasers were provided substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price – the price that corresponded to reported AWPs and inflated reimbursements from the government. Composite Exhibit "8" highlights these inducements:

AOR/PHARMACIA & UPJOHN PARTNERSHIP PROPOSAL: Medical Education Grants. A $55,000 grant has been committed for 1997 for the AOR Partnership for excellence package including Education/Disease Management, Research Task Force, AOR Annual Yearbook. A $40,000 grant to sponsor the AOR monthly teleconference. This sponsorship was committed and complete in February 1997 . . .

PHARMACIA & UPJOHN, INC. INTEROFFICE MEMO:

> If needed, you have a "free goods" program to support your efforts against other forms of generic doxorubicin . . .
>
> Use your "free goods" wisely to compete against other generic forms of Adriamycin, not to shift the customer to direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin (emphasis added by Rep. Stark).

(P007613-P007632). ¶ 463.

And the AMCC identifies internal documents showing marketing of the spread:

In 1997, Pharmacia sent to a clinic a proposal listing the AWP and the contract price at which several drugs would be sold to the provider. The differences are staggering and just a few are noted below:

Drug	AWP	Suggested New Contract Price
Adriamycin (10 mg)	46.00	7.50
Adriamycin (50 mg)	230.00	37.50
Neosar (2 g)	86.00	18.00
Toposar (1 g)	1,330.75	120.00
Vincasar (2 mg)	741.50	7.50

(P007615). ¶ 465.

If that is not enough detail, the AMCC identifies the differences between Red AWP and posted AWP for many other drugs:

Drug	The Pharmacia Group's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Spread
Amphotercin B	$36.26	$16.00	$20.26	127%
Bleomycin Sulfate	$309.98[20]	$158.67	$151.31	96%
Clindamycin Phosphate	$93.60	$61.20	$32.40	53%
Cyclophospamide	$6.29	$3.92	$2.37	60%
Cytarabine	$8.98	$4.06	$4.92	122%
Doxorubicin HCL	$1104.13	$150.86	$953.27	632%
Etoposide	$157.65	$9.47	$148.18	1,565%

[20] Calculation based on the AWP listed in the 2000 *Red Book*.

Fluorouracil	$3.20	$1.47	$1.73	118%
Hydrocortisone Sodium Succinate	$2.00	$1.55	$.45	29%
Metholprednisolone Sodium Succinate	$2.05	$1.45	$.60	41%
Testosterone Cypionate	$17.01	$11.79	$5.22	44%
Vincristine Sulfate	$43.23	$5.10	$38.13	748%

2. The Pharmacia Group-specific arguments lack merit

a. Association standing

This is addressed *infra* at Section III.D.

b. A claim has been stated with respect to Celebrex

Pharmacia spends a portion of its motion on just one of the drugs at issue, Celebrex. The gist of its argument is that as Celebrex is mentioned only a few times in the complaint, it is not enough. Like the other defendants, Pharmacia ignores the Order that directed how Plaintiffs should comply with 9(b), and plaintiffs did so. And it ignores all of the general allegations relating to Pharmacia, the AWP scheme, and Pharmacia's role in marketing the spread.

R. Schering-Plough Group (Schering and Warrick)

1. Review of Schering-Plough allegations

In the AMCC, Plaintiffs allege specific facts against Schering-Plough Corporation ("Schering"), which includes Warrick. Specifically, the AMCC states, and several governmental investigations have confirmed, that Schering created and implemented a fraudulent scheme to artificially elevate prices charged for 27 specific drugs and substantially increased the sales volume and market share of those drugs at those elevated prices.

Schering Plough is the target of a criminal investigation involving: (i) providing remuneration, such as drug samples, to providers to induce the purchase of Schering products for which payment was made through federal health care programs; (ii) selling

misbranded or unapproved drugs; (iii) submitting false wholesale pricing information for its pharmaceutical products to the government; and (iv) destroying evidence and obstructing justice relating to the government's investigation. ¶ 478. During the investigations, the Texas Attorney General's investigators determined that Schering provided the greatest "spread" amongst the drug companies selling albuterol in Texas, and thereby obtained the largest market share for albuterol. The Schering-Plough Group sold a box of albuterol to pharmacies for $13.50, while it charged the Texas Medicaid program $40.30, a 200% increase. ¶ 479.

According to Schering's own documents, the published AWPs for most of its drugs were higher than the actual prices provided to wholesalers. ¶ 485. As a matter of fact, in response to government subpoenas, Schering produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. *Id.* Further, in a report published by the Department of Health and Human Services, the Department of Justice documented at least one instance where the published AWPs for various dosages of albuterol sulfate manufactured by Schering were substantially higher than the actual prices listed by wholesalers. ¶ 487.

In addition to marketing the spread, Schering utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Schering provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

As set forth in the AMCC, Schering's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

2. Review of Warrick allegations

In the AMCC, Plaintiffs allege specific facts against Warrick Pharmaceuticals, Inc. ("Warrick"). Specifically, the AMCC states that Warrick, as part of the Schering Plough Group engages in an organization-wide and deliberate scheme to the inflate AWPs of its drugs. ¶ 476. On October 11, 2001, the West Virginia Attorney General filed suit against Warrick, alleging that Warrick defrauded state agencies and citizens by deliberately overstating the AWP for certain drugs, including albuterol, from approximately 1995 until December 2000. ¶ 480.

Warrick, through the Schering Plough Group, has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, on February 23, 1995, Warrick sent a letter to First Data Bank, stating:

[redacted]

¶ 481.

Defendant Warrick's own communications reveal the extent of the egregious spread perpetrated in their fraudulent pricing scheme. According to Warrick's own documents, Warrick consistently maintained a spread between the AWPs and the direct prices it offered for its albuterol products [redacted]. ¶ 483.

Equally damning are documents produced as a result of the government's investigation of Warrick's fraudulent AWP pricing scheme. In response to government subpoenas, The Schering Plough Group produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other

intermediaries. A review of those price lists reveals that Warrick has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

Those drugs for which Plaintiffs allege Warrick, through the Schering Plough Group, has stated fraudulent AWPs have been set forth in Appendix A to the AMCC, designated by Manufacturer, Product Name, Generic Name, NDC number, fraudulent AWP for specified years. *See* Appendix A. Further, Appendix B to the AMCC identifies those employee welfare benefit plans and employee benefit plans that have been victimized by Defendant Warrick's' deliberate and organization wide scheme to fraudulently inflate the Average Wholesale price for their drugs. *See* Appendix B.

Warrick's misdeeds have not gone unnoticed by Congress. As stated in a May 4, 2000, letter from U.S. Rep. Tom Bliley, Chairman of the Congressional Committee on Commerce, to Raman Kapur, President of Warrick:

> I am writing to you because one of the drugs reflecting a significant variation between the AWP-based prices paid by Medicare and the prices generally charged to private sector purchasers is albuterol sulfate, a drug manufactured by Warrick Pharmaceuticals.

In his May 4, 2000, letter, Bliley outlined The Schering Plough Group's scheme with respect to the prescription drug albuterol sulfate. The government's investigation uncovered a significant spread between the amount Medicare reimbursed for albuterol sulfate and the amount the Schering-Plough Group actually charged. U.S. Rep. Bliley stated:

> The OIG [Office of the Inspector General] has determined that the Medicare-allowed amount for albuterol sulfate, a pharmaceutical product sold by your company, in the Fiscal Year 1996 was $.42. The OIG further estimated that the actual wholesale price of this drug was $.15 and the highest available wholesale price that the OIG was able to identify was $.21.

¶¶ 488 and 489.

As set forth in the AMCC, Warrick through the Schering Plough Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

3. The Schering Plough/Warrick-specific arguments lack merit

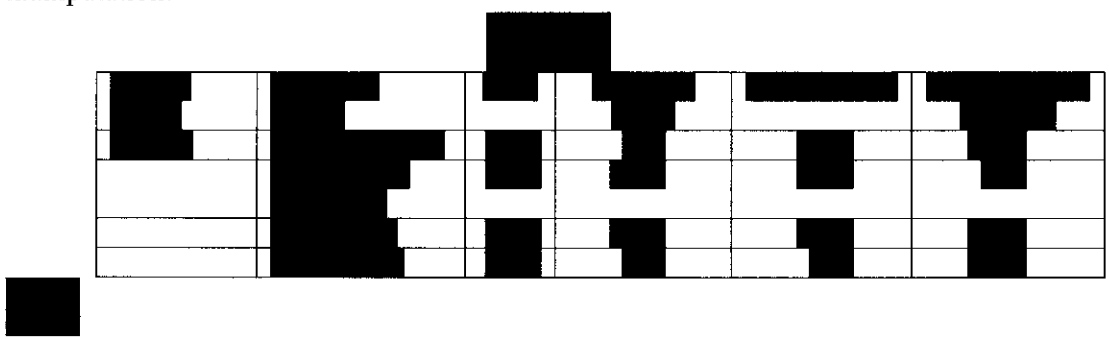
a. Standing

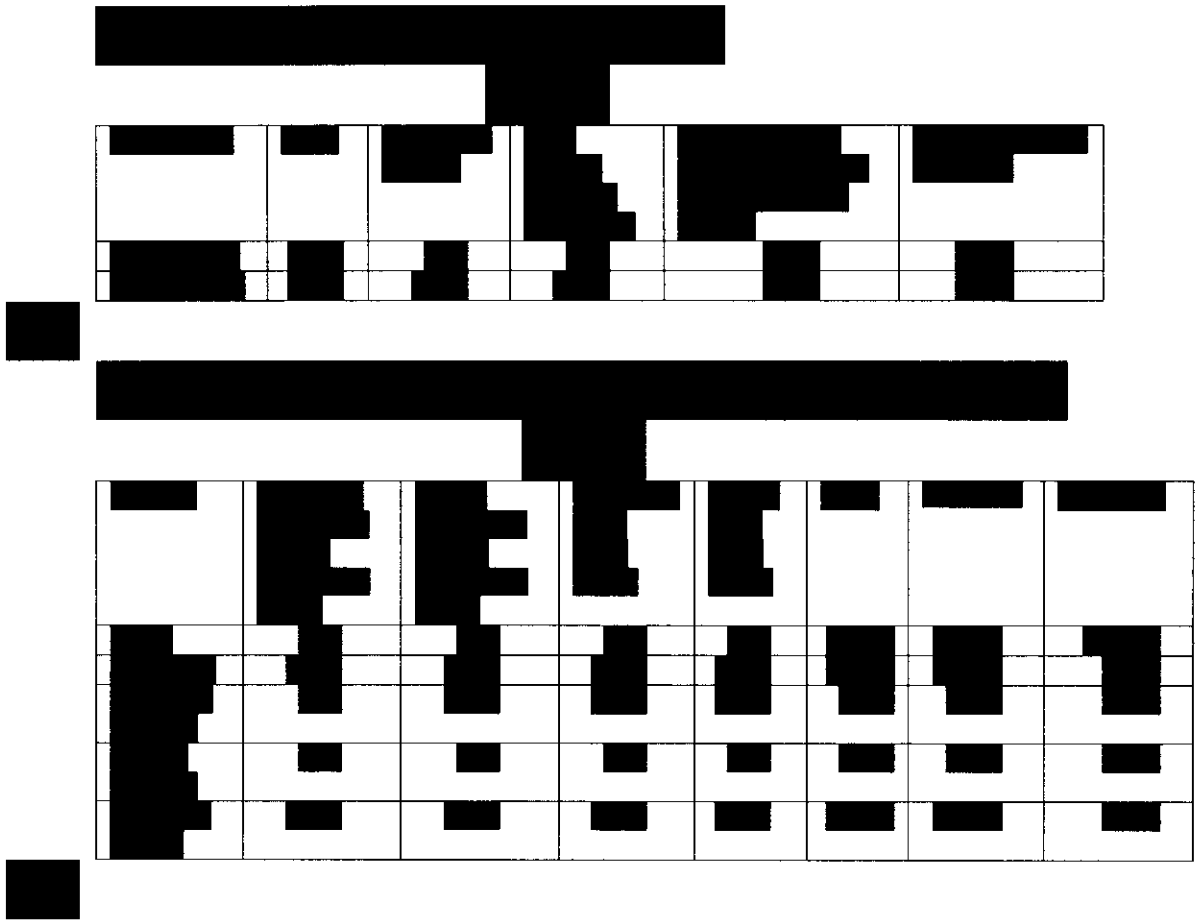
Schering largely repeats the arguments made previously as to standing. For example, Schering's claim that the listing of the AWP for each Schering drug is not in compliance with the Order. Schering at 3. That has been addressed throughout Plaintiffs' opposition. Schering complains that Plaintiffs must allege the prices paid for each drug. That has been addressed repeatedly. *See* Section III., B., and Consolidated Mem. at Section IV.

b. Rule 9(b)

Next Schering argues that with the exception of Proventil no specific allegations are made. Yet Schering ignores the general outline of the scheme as required by Rule 9(b); the identification of governmental reports throughout the AMCC documenting AWP abuse in the generic-multi-source and brand name markets and ignores the specific fining that albuterol sulfate was one of the drugs highlighted by the GAO as a drug whose AWPs were inflated.

As to the Warrick portion of Schering, the AMCC documents examples of AWP manipulation:





Schering-Warrick are silent as to these specifics.

c. Multi-Source Drugs

This argument has been repeatedly made by defendants as to whether multi-source drugs are within the AWP Scheme. It is worth noting, however, that Warrick's own documents again belie the argument, improperly advanced on a motion to dismiss, that the AWP Scheme makes no sense in the generic-multi-source market. As Table 1 quoted above indicates, paragraph 486, use of the spread in the generic market did work and was being utilized by Warrick. And Table 2, documents its use in the non Part B market.

Warrick argues that the allegations as to non-Medicare Part B drugs are "vacuous." In doing so Warrick ignores completely paragraphs 168-178 of the AMCC

that detail the AWP Scheme outside of Part B. And of course Table 3 above evidences use of inflated AWPs in the PBM context.

d. Standing

The standing argument has been addressed throughout the opposition.

S. Sicor

1. Review of Sicor allegations

In the AMCC, Plaintiffs allege specific facts against SICOR, Inc. and Gensia Sicor Pharmaceuticals, Inc. ("Sicor"). Specifically, the AMCC states, and several governmental investigations have confirmed, that Sicor created and implemented a fraudulent scheme to artificially elevate prices charged for seven specific drugs and substantially increased the sales volume and market share of those drugs at those elevated prices. The seven drugs, for which Plaintiff alleges Sicor has stated fraudulent AWPs, have been set forth in Appendix A to the AMCC and Appendix B to the AMCC references those specific Employee Benefit Plan Plaintiffs that purchased any of the seven drugs manufactured by Sicor.

The Amended Complaint alleges that Sicor has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. ¶ 494. Moreover, Sicor has told its sales force to rely on the AWP information contained in the industry compendia when marketing to customers. ¶ 495. Sicor's marketing strategies further demonstrate its fraudulent practices. In a marketing document prepared by Gensia and obtained by the government in its investigation, Gensia stated "Concentrate field reps on the top 40 AIDS hospitals using a $54.00 price in conjunction with a 10% free goods program to mask the final price. Provides the account with an effective price of $48.60 per vial." ¶ 497. Moreover, because Gensia knew that marketing the spread was in its best interests, it even

disseminated advertisements that actually contained a comparison of the Contract Price with the AWP and set forth the resulting spread. ¶ 500.

The AMCC cites to instances where Sicor marketed the spread "Gensia's products offer a significant spread between AWP and contract price. This spread may be attractive, when a payor's reimbursement is based on AWP and the drug is not mac'd." ¶ 500. (Highly Confidential.) And the AMCC provides examples of how Sicor used the scheme to establish spreads as high as 1,964%; 1,648%; 1,415% and 4,802%.

As set forth in the AMCC, Sicor' scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

2. The Sicor-specific arguments lack merit

a. Standing

First, Sicor complains as to standing noting that only one drug was purchased by a Plaintiff of those listed in Appendix A. Of that drug the AMCC estimates a spread at times as high as 4,802%. *See* ¶ 501. As to standing for the other drugs identified in the compliant, this argument has been addressed.

Second, Sicor claims the AMCC fails because it does not identify "where" the drugs were purchased. This was not required by the AWP Order and would again exceed any pleading requirement imposed under the First Circuit and district court cases cited above. *See infra* III., B. and Consolidated Opposition at Section IV.

Third, Sicor's multi-source argument has been addressed elsewhere.

T. TAP Pharmaceutical

1. Review of TAP Pharmaceutical allegations

In the AMCC, Plaintiffs allege specific facts against TAP Pharmaceuticals, Inc. ("TAP"). Specifically, the AMCC states that TAP engages in an organization-wide and

deliberate scheme to inflate AWPs. ¶ 506. Specifically, TAP has stated fraudulent AWP's for Prevacid, as set forth in Appendix A to the AMCC. Moreover, Exhibit B to the AMCC lists those employee welfare and benefit funds that were victimized by TAP's fraudulent pricing scheme.

TAP's egregious track record regarding its inflation of AWPs is well known. On October 13, 2001, the United States Attorney in Boston, Massachusetts announced that TAP had agreed to pay $875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing practices for the drug named Lupron®. ¶ 508.

At a hearing in the criminal matter, which has an extensive record, United States District Court Judge William G. Young found:

> This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

United States v. TAP Pharm. Prods., Inc., No. CR-01-10354-WGY (D. Mass. Dec. 6, 2001); ¶ 509.

TAP's track record does not end here. In addition to marketing the spread, TAP has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. For example, TAP has pled guilty to illegally conspiring with medical providers to provide free samples, which would then be billed, to Medicare. In an October 3, 2001, press release that referenced the guilty plea, TAP's president, Thomas Watkins, stated:

> We admit that TAP provided free samples of Lupron to a number of physicians, primarily in the early to mid-1990s, with the knowledge that those physicians would seek and

> receive reimbursement. The billing for free samples is wrong, and it should never have happened.

TAP has also provided and/or arranged for many other non-public financial inducements to stimulate the sales of its drugs at the expense of Plaintiffs and the Class. Such inducements included volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and grants. All of these incentives are designed to lower the cost of the drug to the medical provider while concealing the actual cost from Plaintiffs and the Class. ¶¶ 515-17.

As set forth above, TAP's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

2. The TAP Pharmaceuticals-specific arguments lack merit

TAP argued that it "is not and has never been a member of Together Rx" and that therefore the Complaint should be dismissed under Rule 12(b)(6). However, the allegations of the AMCC control, and those allegations allege (and the Plaintiffs quite clearly intend to prove) that TAP has engaged in a conspiracy with the other Together Rx Defendants, and that it has actively participated in a Together Rx conspiracy. That should be sufficient.

However, TAP goes on to argue that certain website information reveals that "TAP is not a member of Together Rx," that TAP is mentioned "only as the owner of the trademark of Prevacid" and that it is not a member of Together Rx. Although is it inappropriate to engage in rank factual disputes in the 12(b)(6) context, it cannot go unmentioned that TAP's rendition of the facts is simply wrong. One of the marquee Together Rx Card drugs is Prevacid, a drug manufactured by TAP (as part of the Takeda Abbott co-venturing which forms TAP itself). Indeed, TAP's own website touts its participation in the Together Rx Card program. TAP cannot obtain dismissal of the

allegations of the Complaint simply by trying to deny them (particularly in the face of quite clear contrary proof).

TAP also argues, through citation to *Schwartz v. Celestial Seasonings, Inc.*, 124 F. 3d 1246 (10th Cir. 1997) that the Plaintiffs are required to "specify the consequences of the alleged fraud." In fact, *Schwartz* does not stand for the sweeping proposition urged by TAP. Instead the *Schwartz* Court simply observed: the requirements of Rule 9(b) must be read in conjunction with the principle of Rule 8, which calls for pleadings to be 'simple, concise, and direct, . . . and to be construed as to do substantial justice.' Fed. R. Civ. P. 8(e), (f) [additional citation omitted]. The purpose of Rule 9(b) is to afford Defendant fair notice of the Plaintiffs' claims and the factual ground upon which they are based. . . ." *Schwartz*, 124 F. 3d at 1252.

Plaintiffs respectfully submit that the remaining TAP arguments have been addressed elsewhere.

U. Watson's Specific Arguments

1. Review of Watson-Specific Allegations

In the AMCC, Plaintiff alleges specific facts against Watson Pharmaceuticals, Inc. ("Watson"). Specifically, the AMCC states that Watson engages in an organization-wide and deliberate scheme to inflate AWPs. Watson has stated fraudulent AWPs for all or almost all of its drugs, including: Ferrlecit, Verapamil HCL, Vinblastine Sulfate, Vincristine Sulfate, Dexamethasone, Diazepam, Gentamicin, Testosterone Ethanate, Vancomycin, Fluphenazine, Gemfibrozil, Imipramine, Nadolol, and Perphenazine. ¶ 526. The 17 drugs for which Plaintiff alleges that Watson has stated fraudulent AWPs, have been set forth in Appendix A to the AMCC and the employee welfare and employee benefit plans victimized by Watson's fraudulent pricing scheme are listed in Appendix B to the AMCC.

Morover, the AMCC alleges Watson has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In a memo, Watson states that it is faxing prices to various pricing services, but "not all pricing services received all of the prices listed on this letter. Most only received the AWP price. . . ." The memo goes on to state that "AWP is the primary price being communicated in these faxes to establish a reference for reimbursement." ¶ 529. In a report published by the DHHS (AB-00-86), the DOJ documented at least 12 instances where the published AWPs for various dosages drugs manufactured by Watson were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Watson in the *Red Book*.

Drug	Watson's 1998-2001 *Red Book* AWPs	DOJ Determined Actual AWP	Difference	Spread
Dexamethasone Acetate	$46.45 (1998)	$11.50	$34.95	304%
Dexamethasone Sodium Phosphate	$93.04 (2001)	$1.08	$91.96	851%
Diazepam	$18.15 (2000)	$2.50	$15.65	626%
Gentamicin Sulfate	$114.10 (1999)	$1.18	$112.92	957%
Iron Dextran	$377.04 (2001)	$24.69	$352.35	1,427%
Testosterone Ethanate	$42.10 (2001)	$13.39	$28.71	214%
Vancomycin HCL	$70.00 (1998)	$3.84	$60.16	1,567%

¶ 534.

In addition to marketing the spread, Watson has utilized other inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. In one instance in May 2000, Schein offered "Priority Customers" an additional 5% discount on Ferrlecit "off invoice" for all purchases made that month. By utilizing "off-invoice" inducements, Watson provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price. ¶ 538.

As set forth above, Watson's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

2. The Watson-specific arguments lack merit

Watson's "specific" arguments are in fact repetitive of issues raised in at least 20 other "specific memoranda." Plaintiffs incorporate by reference the previous responses.

By_____
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DATED: September 15, 2003.

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CERTIFICATE OF SERVICE

I hereby certify that I, Edward Notargiacomo, an attorney, caused true and correct copies of the foregoing Plaintiffs' Separate Memorandum of Law in Opposition to Defendants' Specific Motions to Dismiss the Amended Master Consolidated Class Action Complaint (Redacted) to be served on all counsel of record electronically, pursuant to Section D of Case Management Order No. 2., this 15th day of September, 2003.

By: 

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